EASTMAN

Protect devices against aggressive oncology treatments

The new challenges of chemical resistance and FDA regulations

Advanced oncology drugs can test the chemical resistance of polymers in delivery devices — but Eastman Tritan™ copolyester can withstand those challenges.

Since 2016, Tritan has had zero recalls or failures.

Some oncology chemotherapies — the cancer drugs as well as the carrier solvents that help them work effectively — are not compatible with traditional polymers used in delivery devices.

These conditions can prevent the devices from properly doing their job or cause them to fail prematurely. Failure may appear as leaking, cracking or discoloration, which can compromise dosing accuracy, sterility or mechanical integrity. When there is a pattern of compromised device performance or life cycle, regulatory agencies may tell manufacturers to stop using certain materials to protect the well-being of patients.

The stakes are critically high.

Device manufacturers have more reasons than ever to understand the chemical resistance of the materials they use in devices, including the following.

1. The widespread use and economic importance of oncology drugs
   - Worldwide spending on cancer treatments reached **$252 billion** in 2024.[1]
     - — A 74% concentration in major developed markets (U.S., EU4+UK and Japan) has remained stable over the past five years.
     - — Spending is up 152% from 2014 to 2024.
     - — Cancer-medicine spending (excluding additional medical costs and supportive-care medicines) rose 75% over the last five years.
   - Growth in spending averaged 11.9% annually from 2020 to 2024, with a temporary slowdown in 2022 as countries recovered from COVID-19 and treatment volumes flattened.[1]
   - Cytotoxic medicines accounted for 73% of all cancer treatment days of therapy worldwide in 2024.[1]
   - U.S. oncology spending rose from $62B in 2019 to $116B in 2024 (46% of the global total) and is projected to approach $195B by 2029.[1]
   - Cancer medicine spending at list prices is expected to reach $441B by 2029.[1]
   - It is predicted that there will be more than 35 million new cancer cases in 2050 — a 77% increase from roughly 20 million in 2022.[2]

You will learn about:

- The growing therapeutic and economic importance of oncology drug therapy
- The implications of an FDA Safety Alert for oncology drug devices
- How engineering polymers compare for compatibility with oncology drugs and carrier solvents

2. An FDA Safety Alert[3] concerning infusion devices made with polycarbonate (PC) or acrylonitrile butadiene styrene (ABS)

   In March 2015, the FDA and the Institute for Safe Medication Practices (ISMP) issued warnings to healthcare professionals to stop using the chemotherapy drug bendamustine (TREANDA®, Teva Pharmaceutical Industries) with closed-system transfer devices (CSTDs), adapters and syringes containing PC or ABS.

   Read inside for details behind these warnings and their implications for chemical resistance in cancer drug delivery devices.

[1] "Global Oncology Trends 2025: Adopting New Therapies as Modalities Shift and Expenditures Rise." IQVIA Institute for Human Data Science, May 2025. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-oncology-trends-2025. Accessed Oct. 1, 2025.

[2] "Global cancer burden growing, amidst mounting need for services," World Health Organization, Feb. 1, 2024. https://www.who.int/news/item/01-02-2024-global-cancer-burden-growing--amidst-mounting-need-for-services. Accessed Oct. 1, 2025.

[3] FDA MedWatch 10 March 10, 2015 (updated Sept. 8, 2015). Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-against-using-treanda-injection-solution-closed-system-transfer-devices-adapters-and. Accessed Oct. 1, 2025.

Understanding chemical resistance can inform polymer selection.

Engineering polymers offer many advantages for infusion and blood contact devices compared with other materials. Advantages include design and color flexibility, aesthetic appeal, reduced weight, corrosion resistance and clarity.

However, polymers that have a low level of compatibility with chemicals such as lipids, disinfectants and specific oncology drugs and solvents can experience environmental stress cracking (ESC) or premature device failure in the presence of applied or residual stress.

With the goal of improved patient safety, all stakeholders can help reduce the risks of product failure — and help find safe alternatives through:

- Vigilance by regulatory agencies
- Chemical resistance research by polymer manufacturers
- Informed polymer selection for oncology drug delivery devices

Evaluating polymers for chemical resistance.

If DMAc is incompatible with PC and ABS, what about other carrier solvents? What about the oncology drugs themselves? Are there polymer alternatives that offer greater chemical resistance?

These are some of the questions Eastman wanted to answer with a series of chemical resistance tests. Testing recognized that chemical resistance involves more than chemical compatibility — it measures the ability of a material to withstand exposure to a chemical with the addition of stress. The process also considered these factors associated with chemical attack:

- Chemical concentration/exposure time
- Reduced energy required for disentanglement (solvation/plasticization)
- Reduced rigidity, clarity and modulus
- Dynamic fatigue (cyclic loading)

Regulatory vigilance at work — the success story behind the FDA Safety Alert[1]

- N, N-dimethylacetamide (DMAc) is a carrier solvent ingredient used in bendamustine as well as the cancer drugs amsacrine and busulfan[2].
- According to the FDA, devices that contain PC and ABS dissolve when they come in contact with DMAc.
- This incompatibility in oncology drug delivery devices can pose serious risks, including:
  - Leaking
  - Breaking
  - Operational failure of the CSTD components
  - Possible contamination of the drug
  - Potential adverse health consequences to practitioners (skin reactions)
  - Potential adverse consequences to patients if dissolved PC or ABS enters the patient's vascular system
- The FDA continues to provide updates about compatibility.

[1] FDA MedWatch March 10, 2015 (updated Sept. 8, 2015). Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-against-using-treanda-injection-solution-closed-system-transfer-devices-adapters-and. Accessed Oct. 1, 2025.

[2] "Chemotherapy May 'Melt' Some CSTDs," Pharmacy Practice News, April 2015 | Volume 42. Available at: https://www.pharmacypracticenews.com/Clinical/Article/04-15/Chemotherapy-May-Melt-Some-CSTDs/31083. Accessed Oct. 1, 2025.

Testing methodology

- Eastman used a modified ASTM D543 test for evaluating chemical resistance.
- Tests compared flex bar samples molded from PC, impact modified styrenic and Tritan copolyester.
- Samples were exposed to various oncology drugs and carrier solvent chemicals for 24 hours while being held under 1.5% strain.
- After exposure, the samples were impacted with a pendulum hammer to measure the energy required to break them.

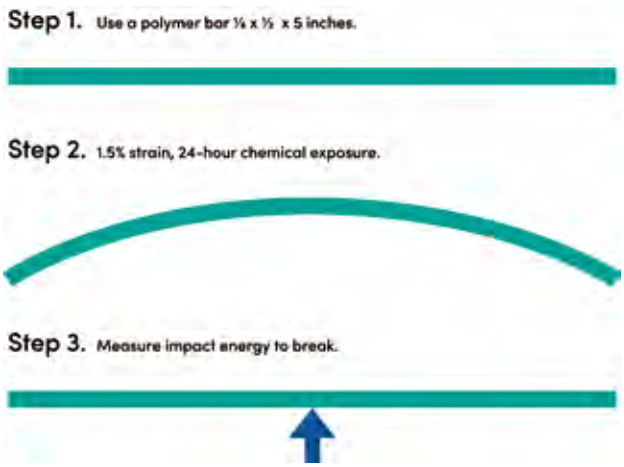

Table 1. Residual property evaluation: *Impact properties against oncology drug carrier solvents*

Materials	Control (joules)	MCT oil[a]	Etoposide carrier solvent[b]	Busulflex® carrier solvent[c]	Dimethylacetamide	Median
		% Retention of impact energy to break				
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
Polycarbonate (high flow)	5.3	7[d]	All broke on jig.	All broke on jig.	All broke on jig.	All broke on jig.
Polycarbonate (standard)	5.4	34[d]	12 ± 1	All broke on jig.	All broke on jig.	All broke on jig.
Polycarbonate (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]	6 ± 1[f]	Severe surface attack	9[e]

> 80% retention > 60% retention < 60% retention

[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]3 of 4 samples broke on jig. Standard deviation not calculated.
[e]2 of 4 samples broke on jig. Standard deviation not calculated.
[f]1 of 4 samples broke on jig.

Results — against oncology drug carrier solvents

- Table 1 shows the results of exposure to DMAc (the solvent implicated in the FDA Safety Alert) and four other common solvents.
- All solvents were very aggressive on the engineered polymers.
- Grades of Tritan offered a higher level of property retention.
- Tritan MX711 offers significantly better chemical resistance compared to PC and impact modified styrenic, which is chemically similar to ABS.

Table 2. Residual property evaluation: *Impact properties against oncology drugs*

Materials	Control (joules)	Taxol®	Etoposide	Ifex®	Methotrexate	Cyclophosphamide	Adriamycin®
		% Retention of impact energy to break					
Tritan 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
Polycarbonate (high flow)	5.3	All broke on jig.	48 ± 46	28 ± 43	54 ± 58	104 ± 2	101 ± 11
Polycarbonate (standard)	5.4	12[a]	66 ± 44	87 ± 41	101 ± 1	114 ± 2	104 ± 3
Polycarbonate (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[f]	100 ± 1	100 ± 1	10 ± 2

> 80% retention > 60% retention < 60% retention

[a]2 of 4 samples broke on jig. Standard deviation was not calculated.

Reference: Chemical resistance advantages of Tritan copolyesters for medical—Oncology drug case study, ANTEC 2014, 1812

Results — against oncology drugs

- Table 2 shows the results of exposure to six popular oncology drugs.
- Generally, results were much better than in Table 1.
- Overall, grades of Tritan offered a higher level of chemical resistance.

Summary

Eastman Tritan copolyesters have good overall chemical resistance and provide an attractive alternative to PC or ABS for oncology drug delivery devices. For CSTDs and other infusion devices, Tritan can be a candidate for molding devices that are compliant with FDA and ISMP Safety Alerts.

To evaluate polymers for your specific FFU requirements, it's important to consider these results — as well as actual testing of articles molded for the intended application. Eastman technical specialists are prepared to help you early in your process to produce high quality medical devices.

For additional results of tests comparing compatibility with medical disinfectants and disinfectant wipes or color shifting after sterilization with ethylene oxide or gamma irradiation, visit www.info.eastman.com/tritan_medical

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