

# Supporting your confidence

*with product stewardship  
and product safety studies*



# Confidence is a key ingredient in Eastman Tritan™ copolyester.

## Confidence is important throughout the value chain.

Consumers have questions about the safety of the products in their lives. This leads to a stronger desire for reliable information about what goes into the products they purchase and use every day. Brand owners and manufacturers who are prepared to share information that cultivates consumer confidence can tap into the growing customer demand for assurance that products are both safe and reliable.



As a leader in technology and innovation, Eastman takes the relationship between understanding and confidence very seriously.

- This includes conducting extensive internal and third-party studies that help customers and the public understand our products and address potential safety concerns.
- It also includes addressing competitors' misinformation and redoubling Eastman's commitment to rely on sound science and research, and transparent communications along the supply chain and those who use our products in their various food contact articles or applications.

The results of independent third-party testing are summarized in this brochure. These results confirm that Eastman Tritan™ copolyester is free from bisphenol A (BPA). In addition, separate comprehensive third-party testing using well-recognized scientific methods demonstrates that Tritan is free of estrogenic activity (EA) and androgenic activity (AA).



## Product stewardship is critical throughout the production stream.

Customer confidence in an innovative polymer like Eastman Tritan™ copolyester begins with a strong commitment to product stewardship. To Eastman, this means applying world-class product development and production processes to ensure the safety of our employees and customers.

Eastman's commitment to product stewardship is demonstrated by its compliance with regulatory requirements and ISO standards in its manufacture of Tritan—and Tritan's clearance for use in food contact applications around the world. This commitment is especially evident in an Eastman plant in Kingsport, Tennessee, dedicated exclusively to the production of Tritan. Additional examples of Eastman's product stewardship can be found at [www.TritanSafe.com](http://www.TritanSafe.com).

Eastman understands that an informed consumer can be a more confident consumer—and a more satisfied customer. It also knows there is a lot of confusing misinformation in the marketplace about plastics and their ingredients. Therefore, a critical part of the responsible stewardship of Tritan involves conducting and publishing rigorous studies like those summarized on the following pages to help brand owners maintain the confidence of their employees, investors, and end users.

### DEFINITION OF TERMS

**Endocrine disrupting chemicals (EDCs)**—chemicals that are known to activate or inhibit estrogenic and/or androgenic (testosterone) responses in various species and ultimately lead to adverse health effects.

- **Estrogenic activity (EA)**—activity that specifically mimics the naturally occurring hormone estrogen.
- **Androgenic activity (AA)**—activity that specifically mimics the naturally occurring hormone testosterone.



# Comprehensive safety testing

*supports confidence.*

A comprehensive body of testing conducted by various reputable independent third-party research labs, using well-recognized scientific test methods, evaluated monomers of and/or potential migration products from Eastman Tritan™ copolyester based on three complementary approaches:

1. Structural evaluation of monomers of Tritan compared with estrogenic compounds
2. *In vitro* testing of monomers and extracts to determine whether any compounds with endocrine disrupting potential migrate from Tritan copolyester
3. *In vivo* testing to evaluate the potential of Tritan monomers to induce or mimic EA and AA in a living animal

Based on results from this battery of tests, Tritan is free of EA and AA. More details on these tests follow.

## Structural evaluation of monomers

EDCs mimic naturally occurring estrogen and testosterone present in the body to such an extent that they induce potentially adverse biological activity. This occurs because EDCs can bind to estrogen and androgen receptors found within cells, similar to a lock and key mechanism. The monomers used to produce Tritan were assessed for their ability to bind to these receptors. This was accomplished using computerized Quantitative Structural Activity Relationship (QSAR) modeling programs. QSAR modelling compares the structural and chemical characteristics of the monomers against compounds with known estrogenic or androgenic activity.

Results of this research, conducted by the UMDNJ-Robert Wood Johnson Medical School,<sup>1</sup> indicate that monomers used to produce Tritan have negligible binding affinity with estrogen and androgen receptors.

<sup>1</sup> Conducted by Dr. William Welsh, Department of Pharmacology, UMDNJ-Robert Wood Johnson Medical School, Piscataway, N.J.



## ***In vitro* testing of monomers and potential migration products**

Despite an extremely low likelihood for monomers of Eastman Tritan™ copolyester to bind to receptors based on their structure and the QSAR computer modeling studies, additional laboratories assessed the EA and AA of both the monomers and concentrated extracts of Tritan.<sup>2,3</sup>

Using tests known as the Relative Binding Assay and the Receptor Transactivation Assay, the functionality of any binding that may result from exposure to Tritan monomers or their extracts was evaluated. Migration products from Tritan were obtained from several grades of Tritan using rigorous extraction techniques and conditions consistent with use of the material in baby bottles and food contact applications.

Migration products collected from these extractions were then incubated in a bioluminescent yeast assay that responds to (i.e., detects) the presence of estrogenic and androgenic compounds.

Results of this *in vitro* testing showed no estrogenic or androgenic response.

## ***In vivo* testing for EA and AA**

Even though the *in vitro* tests found no EA or AA, a third series of tests were conducted to evaluate the potential of Tritan monomers to elicit an estrogenic or androgenic response in biological systems.<sup>4</sup>

These *in vivo* tests included the Uterotrophic and Hershberger assays for assessing potential to elicit EA or AA, respectively. These tests are regarded by the scientific community to be very sensitive in their ability to detect compounds that possess EA or AA and are considered the "gold standard" for assessing the endocrine disrupting potential of a compound. In fact, both methods are accepted tests in the Tier I Endocrine Disruption Screening Program of the U.S. Environmental Protection Agency (EPA).

Monomers used in Tritan were given orally as a mixture and encompassed a wide range of doses. EA and AA were assessed by examination of reproductive organs and other tissues for any change in weight or appearance as required by these specific assays. Results from these tests showed no evidence of estrogenic or androgenic effects in any of the measured tissue parameters.



These third-party results demonstrate that Tritan is free of EA and AA. The monomers and potential migrants of Tritan do not demonstrate an affinity to bind to hormone receptors or a potential to induce endocrine disrupting effects. The result of the monomer studies assessing endocrine activity and a detailed explanation of this scientific approach have been published in *Food and Chemical Toxicology*, Vol. 5, Issue 2, pages 2196–2205 (2012).

<sup>2</sup> Conducted by CeeTox Inc., Kalamazoo, Michigan

<sup>3</sup> Conducted by the Center for Environmental Biotechnology, University of Tennessee, Knoxville, Tennessee.

<sup>4</sup> Conducted by WIL Research Laboratories, LLC, Ashland, Ohio

# Testing confirms BPA is not present in Eastman Tritan™ copolyester.

In response to market demand for a BPA-free and BPA analog-free alternative, many brand owners and molders are looking to Tritan as a high-performance solution. To increase customer confidence in the decision to use Tritan, Eastman has gone the extra step of rigorously analyzing this innovative polymer—and making test results available to customers.

Most importantly, no BPA or any analogs such as BPS, have ever been used as a raw material in the manufacture of Tritan nor are formed as by-products in the manufacturing process. Validation that Tritan is BPA free is supported by robust internal testing and independent third-party testing by accredited laboratories.<sup>5</sup> Third-party tests were conducted with a limit of detection as low as 0.01 ppm, and the results indicate that Tritan, as supplied by Eastman, has been found to be free of BPA. In addition, no BPS was detected in third-party testing with a limit of detection of 30 ppm.

Eastman has also developed “depolymerization testing” using a robust analytical method in which the Tritan polymer matrix is hydrolyzed into its starting monomers. When Tritan resin is tested using this robust method, no BPA has been detected. These results were published in Cleven et al, *Journal of Liquid Chromatography & Related Technologies*, 35(8), 1102–1113 (2012).

<sup>5</sup> Intertek, [www.Intertek.com](http://www.Intertek.com).



**For more information about these testing methods and results and to learn more about Tritan safety and stewardship, contact your Eastman representative or visit [www.TritanSafe.com](http://www.TritanSafe.com).**

## Greater confidence in what is NOT present

*Ortho-phthalates are not present in Eastman Tritan™ copolyesters.*

Tritan is free of *ortho*-phthalates plasticizers. Often simply called "phthalates," this group of plasticizers—including DEHA and DEHP—is used to make PVC and other plastic materials soft and flexible for applications such as flexible hoses, tubing, flexible film, roofing materials, electrical cable insulation, and inflatable structures. These materials are quite different from clear, hard plastics like Tritan, whose performance does not require *ortho*-phthalates.

*Tritan is not present on the Prop 65 list.*

As consumers in California know—and manufacturers throughout the world are discovering—Proposition 65 requires that a warning label be provided to employees, manufacturers, and consumers in the state when they are exposed to chemicals at levels that may cause cancer or reproductive harm. Currently, the list of chemicals where a warning may be needed numbers over 800 and includes chemicals, pesticides, and common pharmaceuticals.

For more information and a link to the full list, visit <http://goo.gl/uJV71>.

## MAKING YOUR CONFIDENCE SUSTAINABLE

Eastman's ongoing commitment to product stewardship supports customer confidence through product research and development, technical support, and advances in sustainability.

Eastman's individual innovation and collaboration with other forward-looking Responsible Care® companies, is developing products and programs for the protection of the environment and the health and safety of employees, communities, and people who handle Eastman products.

Learn more at [www.Eastman.com/Sustainability](http://www.Eastman.com/Sustainability).





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