



DuPont Medical and Pharmaceutical Protection  
Chestnut Run Plaza, Bldg. 735  
974 Centre Road  
P.O. Box 2915  
Wilmington, DE 19805

December 20, 2017

## **Open Letter to the Industry: Update on the DuPont™ Tyvek® Medical Packaging Transition Project (MPTP) and Clarification on Interchangeability**

The Medical Packaging Transition Project (MPTP) has two objectives:

- To demonstrate Functional Equivalence between Legacy Tyvek® and Transition Tyvek® produced on our newer manufacturing assets.
- To demonstrate Functional Equivalence and interchangeability of Transition Tyvek® produced on three qualified manufacturing lines.

There are two qualified manufacturing lines in Richmond, VA, and one in Luxembourg. The DuPont Manufacturing Site Teams in the U.S. and Europe have each qualified two polymer sources, which are not interchangeable between manufacturing sites. This results in a total of six line/polymer combinations.

It is important to note that in the MPTP study design, Functional Equivalence is only proven for transitioning from Legacy Tyvek® to Transition Tyvek®. A medical device manufacturer who has only qualified Transition Tyvek® cannot switch to Legacy Tyvek® without first performing the necessary studies to qualify Legacy Tyvek® for that application.

As outlined in our study reports, there are three parts of the MPTP which demonstrate that all line/polymer combinations of Transition Tyvek® 1073B and Transition Tyvek® 1059B are interchangeable for Legacy Tyvek® 1073B and Legacy Tyvek® 1059B, respectively:

1. *U.S. FDA Transition Protocol* – a study plan based on sound principles of experimental design and statistical analysis for generating data to prove Functional Equivalence by comparing three lots of Transition Tyvek® for each of the six line/polymer combinations and Legacy Tyvek® using 60 different device/package combinations (“cells”) with validated package designs, packaging processes and sterilization protocols.
2. *Phantom Protocol* – creation and testing of 18 additional sterilized medical device/ package combinations (“cells”) that are outside the scope of the U.S. FDA Transition Protocol but have been requested by the industry to support risk assessments.
3. Biocompatibility, Food Contact and Pharmacopoeia testing.

Because data from all line/polymer combinations were used to establish the published specification and miscellaneous properties for Transition Tyvek®, DuPont will continue to fill orders from all line/polymer combinations interchangeably, based upon global demand.

As announced earlier in 2017, we will continue to supply Legacy Tyvek®, along with Transition Tyvek®, in North America to meet global demand through 2018. We are expecting a phaseout of manufacturing of Legacy Tyvek® by the end of 2018 or early 2019.

Most of the industry has already made the transition or is ready to transition. We believe that ample notice on MPTP has been given for manufacturers to complete their transition. It has been seven years since the announcement of MPTP; three years since Transition styles have been available for testing; and two years since the U.S. FDA letter of Functional Equivalence was issued. **Therefore, we will give notice of sixty (60) days to the industry when the final production of Legacy Tyvek® 1073B and Legacy Tyvek® 1059B are scheduled.** For this reason, it is essential that all MDMs continue to move forward and complete their change control processes, risk assessments and regulatory submissions to the notified bodies and other regulatory authorities so that they can accept Transition Tyvek®.

Real-time aging studies continue to progress. The 3-Year Real-Time Aging Industry Summary Report is available on our [website](#). The 5-Year Real-Time Aging Reports will be issued in two years and 10-Year Real-Time Aging Reports will be issued in seven years.

Thank you for your business and ongoing engagement. If you have any questions, please contact any member of the DuPont Medical and Pharmaceutical Protection Team.



Margaret Pyers  
Global Business Leader



Joe Dennes, Ph.D.  
Global Technology Director



Michael H. Scholla, Ph.D.  
Global Director, Regulatory &  
Standards  
[michael.h.scholla@dupont.com](mailto:michael.h.scholla@dupont.com)