

Comprehensive List of Testing for DuPont™ Tyvek® MPTP

March 12, 2015

The DuPont™ Tyvek® Medical Packaging Transition Project (MPTP) includes a systematic method for generating data to prove that Transition Protocol material is functionally equivalent in performance to current Tyvek®, in an effort to help mitigate requalification.

This document provides a comprehensive listing of all testing that will be conducted for each of the three MPTP study components:

- U.S. FDA Transition Protocol
- Phantom Protocol
- Biocompatibility, Food Contact and Pharmacopeia Testing

It is designed to help you with your risk assessment and change control management procedures by providing an overview of all MPTP testing in one document.

To date, we have posted a wealth of information on our website (www.areyouready.tyvek.com), including: Transition Protocol Material property data, Phantom Protocol data and Biocompatibility, Food Contact and Pharmacopeia Testing data. We have also posted Industry Summary Reports of package test results for pre- and post-sterilization and for 1-year accelerated aging. In the future, we will post Industry Summary Reports for other MPTP time points, including: 3-, 5-, 7- and 10-year accelerated aging* and 1-, 3-, 5- and 10-year real-time aging.*

In addition, we have created the MPTP Package Test Results Selector Tool, which enables you to search for current results from MPTP testing by selecting Tyvek® style and package design. This tool currently features MPTP package test results for pre-sterilization, post-sterilization and 1-year accelerated aging.

We will continue to share data in future webcasts, post new information on our website and update the MPTP Package Test Results Selector Tool as new data becomes available.

* Eleven cells are designated for 7- and 10-year accelerated aging and for 10-year real-time aging.

DuPont™ Tyvek® MPTP Package Testing

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Protocol	No. of Cells	Package Format†	Sterilization Method*	Test Methods	Tests - Description	Pre-Sterilization	Post-Sterilization	Accelerated Aging Conditions (Years)	Real-Time Aging Conditions (Years)
FDA	6	Coated 1073B Pouches/Bags	EO**	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1, 3, 5	1, 3, 5
FDA	6	Coated 1073B FFS	EO**	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1, 3 In progress: 5	1, 3, 5
FDA	9	Coated 1073B Lids/Rigid Trays	EO**	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1, 3 In progress: 5; one cell 7 & 10 also	1, 3, 5; one cell 10 also
FDA	6	Uncoated 1073B Pouches/Bags	EO**	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1, 3 In progress: 5; one cell 7 & 10 also	1, 3, 5; one cell 10 also
FDA	3	Coated 1073B Pouches/Bags	Gamma	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1, 3, 5 In progress: two cells 7 & 10 also	1, 3, 5; two cells 10 also
FDA	3	Coated 1073B FFS	Gamma	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1, 3, 5 In progress: one cell 7 & 10 also	1, 3, 5; one cell 10 also
FDA	6	Coated 1073B Lids/Rigid Trays	Gamma	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1 In progress: 3, 5; five cells 7 & 10 also	1, 3, 5; five cells 10 also
FDA	3	Uncoated 1073B Pouches/Bags	Gamma	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1, 3 In progress: 5	1, 3, 5
FDA	3	Coated 1073B FFS	Electron-beam	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1 In progress: 3, 5	1, 3, 5
FDA	3	Uncoated 1073B Pouches/Bags	Electron-beam	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1, 3, 5	1, 3, 5
FDA	3	Coated 1059B FFS	EO**	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1, 3, 5	1, 3, 5
FDA	6	Uncoated 1059B Pouches/Bags	EO**	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1 In progress: 3, 5	1, 3, 5
FDA	3	Uncoated 1059B FFS	EO**	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1, 3 In progress: 5	1, 3, 5
Phantom	1	Coated 1073B Pouches/Bags	EO**	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1 In progress: 3, 5	1, 3, 5
Phantom	1	Coated 1073B FFS	EO**	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1, 3, 5 In progress: 3, 5	COMPLETED: 1 In progress: 3, 5
Phantom	2	Coated 1073B Lids/Rigid Trays	EO**	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1 In progress: 3, 5	1, 3, 5
Phantom	1	Uncoated 1073B Pouches/Bags	EO**	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1 In progress: 3, 5	1, 3, 5
Phantom	2	Coated 1073B Lids/Rigid Trays	Gamma	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1, 3 In progress: 5	1, 3, 5
Phantom	1	Uncoated 1059B Pouches/Bags	EO**	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1, 3 In progress: 5	1, 3, 5
Phantom	3	Coated 1073B Lids/Rigid Trays	Steam	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1 In progress: 3, 5	1, 3, 5
Phantom	2	Uncoated 1073B Pouches/Bags	Steam	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1 In progress: 3, 5	1, 3, 5
Phantom	1	Coated 1073B Lids/Rigid Trays	Dry Heat	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1 In progress: 3, 5	1, 3, 5
Phantom	1	Coated 1073B Pouches/Bags	Low Temp. H ₂ O ₂	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1 In progress: 3, 5, 7, 10	1, 3, 5, 10
Phantom	1	Coated 1073B Lids/Rigid Trays	Low Temp. C ₂ H ₄ O ₃	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1 In progress: 3, 5	1, 3, 5
Phantom	1	Coated 1059B FFS	Gamma	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1 In progress: 3, 5	1, 3, 5
Phantom	1	Coated 1059B FFS	Electron-beam	ASTM F1886M, F88‡, F1929, F2638	Visual, Seal Strength, Package Integrity (Dye), Microbial Barrier	COMPLETED	COMPLETED	COMPLETED: 1 In progress: 3, 5	1, 3, 5
Total	78	Coated & Uncoated 1073B & 1059B♦				ALL	ALL	eleven cells 7 & 10 also	eleven cells 10 also

NOTES: † Packages made at upper, lower and nominal sealing conditions for three lots of Transition Protocol material and three lots of current Tyvek®.
 * Sterilization cycles are described in cell descriptors which can be found using the MPTP Cell Descriptor Selector Tool at www.Transition.Tyvek.com.
 ** EO residuals are measured and compared between Transition Protocol material and current Tyvek®.
 ‡ ASTM F88 technique per cell per medical device manufacturer's (MDM's) standard practice.
 ♦ Specific material combinations are described in cell descriptors which can be found using the MPTP Cell Descriptor Selector Tool at www.Transition.Tyvek.com.

Phantom Protocol Material Testing

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Property	Test Method(s)	Sterilization Method/Details	Pre-Sterilization	Post-Sterilization	Accelerated Aging Conditions (Years)	Real-Time Aging Conditions (Years)	Status
MD Tensile Strength & Elongation	ASTM D5034	EO; 25, 50 & 100 kGy gamma; 25, 50 & 100 kGy electron-beam; steam; STERRAD [®] 100S; vapor hydrogen peroxide	COMPLETED	COMPLETED	COMPLETED: 1, 3, 5	COMPLETED: 1	Aging work in progress
					In progress: 7, 10	In progress: 3, 5, 7, 10	
CD Tensile Strength & Elongation	ASTM D5034	EO; 25, 50 & 100 kGy gamma; 25, 50 & 100 kGy electron-beam; steam; STERRAD [®] 100S; vapor hydrogen peroxide	COMPLETED	COMPLETED	COMPLETED: 1, 3, 5	COMPLETED: 1	Aging work in progress
					In progress: 7, 10	In progress: 3, 5, 7, 10	
Puncture Strength	ASTM F1342	EO; 25, 50 & 100 kGy gamma; 25, 50 & 100 kGy electron-beam; steam; STERRAD [®] 100S; vapor hydrogen peroxide	COMPLETED	COMPLETED	COMPLETED: 1, 3, 5	COMPLETED: 1	Aging work in progress
					In progress: 7, 10	In progress: 3, 5, 7, 10	
Microbial Barrier	ASTM F1608	EO; 25, 50 & 100 kGy gamma; 25, 50 & 100 kGy electron-beam; steam; STERRAD [®] 100S; vapor hydrogen peroxide	COMPLETED	COMPLETED	COMPLETED: 5	X	Aging work in progress
					In progress: 10		
Microbial Barrier	ASTM F2638	EO; 25, 50 & 100 kGy gamma; 25, 50 & 100 kGy electron-beam; steam; STERRAD [®] 100S; vapor hydrogen peroxide	COMPLETED	COMPLETED	COMPLETED: 1, 3, 5	COMPLETED: 1	Aging work in progress
					In progress: 7, 10	In progress: 3, 5, 7, 10	
Differential Scanning Calorimetry (DSC)			•	X	X	X	COMPLETED
Attenuated Total Reflectance - Fourier Transform Infrared Spectroscopy (ATR-FTIR)			•	X	X	X	COMPLETED
Area Shrinkage (%) after Steam Sterilization		steam: 121°C, 123°C, 125°C, 127°C, 129°C, 131°C	X	•	X	X	COMPLETED
Gurley Hill Porosity (GHP) after Steam Sterilization	"Modified GHP" ISO 5636-5	steam: 121°C, 123°C, 125°C, 127°C, 129°C, 131°C	X	•	X	X	COMPLETED
Hydrostatic Head (HH) after Low-Temperature Oxidative Sterilization	AATCC TM 127 EN 20811	STERRAD [®] 100S; vapor hydrogen peroxide	X	•	X	X	COMPLETED
Dimensional Stability Study	MD/CD Tensile Strength, Puncture Resistance, Microbial Barrier ASTM F2638	Steam Sterilize - Freeze (-80°C) - Thaw - Freeze (-80°C) - Thaw - Test	X	•	X	X	COMPLETED
Particle Generation	"Modified Gelbo" ISO 9073-10		•	X	X	X	COMPLETED
Printability	Flexography Thermal Transfer		•	X	X	X	COMPLETED
Parker Surface Smoothness			•	X	X	X	COMPLETED
Surface Energy	Contact Angle Dyne Pen		•	X	X	X	COMPLETED
Chemical Resistance	MD/CD Tensile Strength	e.g.: Isopropanol, Iodine, Hydrogen Peroxide, etc.	•	X	X	X	Work in progress
Coefficient of Friction	Dynamic Static		•	X	X	X	COMPLETED
Color	L,a,b Measurements	EO; 25, 50 & 100 kGy gamma; 25, 50 & 100 kGy electron-beam; steam; STERRAD [®] 100S; vapor hydrogen peroxide	•	•	1, 5, 10 [†]	1, 5, 10 [†]	Work in progress
Low-intensity UV Stability	Visual Assessment	EO; 25, 50 & 100 kGy gamma; 25, 50 & 100 kGy electron-beam; steam; STERRAD [®] 100S; vapor hydrogen peroxide	•	•	X	X	Work in progress

NOTES: • = Will be tested
X = Will not be tested
† = Only those sterilization methods shown in red will be tested under these aging conditions.

Biocompatibility, Food Contact and Pharmacopeia Testing*

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Cytotoxicity (ISO 10993-5)	PASS: <ul style="list-style-type: none"> • Pre-sterilization • Post-sterilization and 5-year accelerated aging (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam) 	In progress: 10-year accelerated aging
Endotoxins (USP <85>)	PASS (pre-sterilization)	COMPLETED
Skin irritation and sensitization (ISO 10993-10)	PASS (pre-sterilization)	COMPLETED
Bioburden (ISO 11737-1)	Similar performance to current Tyvek® (pre-sterilization)	COMPLETED
Extractables and leachables (ISO 10993-18: Infrared spectroscopy; ICP-MS; GC-MS; UPLC-MS)	Pre-sterilization: <ul style="list-style-type: none"> • No major bands of interest (Infrared spectroscopy) • Met all requirements (ICP-MS; GC-MS; UPLC-MS) Post-sterilization (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam): <ul style="list-style-type: none"> • No major bands of interest (Infrared spectroscopy) • Met all requirements (ICP-MS; GC-MS) • UPLC-MS testing—see** 	COMPLETED
U.S. Food Contact		
21 CFR 177.1520	PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam)	COMPLETED
U.S. Pharmacopeia		
USP <88> Class VI	PASS (pre-sterilization)	COMPLETED
USP <661>	PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam)	COMPLETED
European Food Contact		
EC Reg. 10/2011	PASS (pre-sterilization, EO, 100 kGy gamma, 100 kGy electron-beam, steam)	COMPLETED
European Pharmacopeia		
EP 3.1.5 and EP 3.1.3	Meets the compositional and extractable requirements (pre-sterilization)	COMPLETED
EP 3.1.5 Selected Testing: (1) Identification A: IR Spectrometry (2) Hexane Solubility	PASS (EO, 100 kGy gamma, 100 kGy electron-beam, STERRAD® 100S, vapor hydrogen peroxide, steam)	COMPLETED

NOTES: * Generated for 1073B and/or 1059B Transition Protocol material and Tyvek® 1073B and/or 1059B current material.

** Under extraction conditions of 70°C for 24 hours in purified water, a compound tentatively identified as an “oxygenated unsaturated hydrocarbon” was found to exceed the 0.1 µg/mL concentration allowance by ~0.01-0.25 µg/mL.