DUPONT™ TYVEK® MEDICAL PACKAGING TRANSITION PROJECT (MPTP) EXECUTIVE SUMMARY — JUNE 2016 – THE FINAL PHASE

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For more information, including links to data and documents, visit our website at www.Transition.Tyvek.com

DUPONT™ TYVEK® MPTP EXECUTIVE SUMMARY

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EXECUTIVE SUMMARY

The DuPont™ Tyvek® Medical Packaging Transition Project (MPTP) is entering its final transition phase for Tyvek® 1073B and Tyvek® 1059B to the latest flash-spinning technology. This program will help provide greater long-term continuity and flexibility of Tyvek®. The MPTP is an extensive collaborative effort involving sterile packaging manufacturers (SPMs), medical device manufacturers (MDMs), regulatory authorities, testing laboratories and contract sterilizers around the world. The success of DuPont™ Tyvek® MPTP would not be possible without this unprecedented industry collaboration.

Over the course of four years, DuPont has heavily invested to bring the medical packaging industry data to demonstrate functional equivalency of these Tyvek® products. More than 125,000 data points later, DuPont and U.S. FDA have affirmed the interchangeability of Tyvek® 1059B and 1073B produced on the original manufacturing lines with Tyvek® 1059B and 1073B produced on the newer manufacturing lines.

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COMMERCIALIZATION

U.S. FDA affirmation of functional equivalence was received on October 1, 2015, signaling the beginning of full commercial availability of Tyvek® produced on the newer manufacturing lines, which is known as Transition Tyvek®. Legacy Tyvek® is the new term for Tyvek® produced on the original manufacturing lines. Both Legacy and Transition Tyvek® are now commercially available from DuPont to SPMs. DuPont will use the terms Legacy Tyvek® and Transition Tyvek® on product literature, reports and other documents going forward. Tyvek® style names 1073B and 1059B remain unchanged.

Recognizing the real-world dynamics of our customers' needs and regulatory submissions, DuPont has made Legacy Tyvek® commercially available through June 2016. It is important to note that each SPM has their own inventory management systems. MDMs should contact their direct Tyvek® supplier for any questions related to the supply of Legacy or Transition Tyvek®.

1. Is the Transition Tyvek® material the same as Transition Protocol Tyvek®?

Yes, Transition Tyvek® used to create the packages for testing, sold for controlled sales (also known as Transition Protocol) and sold commercially today are **ALL** made under the same commercial manufacturing conditions and meet the current Transition Tyvek® quality specifications.

2. Will we be able to get Legacy Tyvek® after June 2016?

If you have a special circumstance requiring Legacy Tyvek® after June, discuss your situation with your supplier to determine how best to meet your needs. Each SPM has their own inventory management system. DuPont is not able to comment on our customer's inventory levels.

3. Is there a benefit to begin using Transition Tyvek® sooner rather than later?

Yes, using Transition Tyvek® provides the customers an additional asset to supply the growing marketplace.

4. What conditions have to be fulfilled to use Legacy Tyvek® and Transition Tyvek® interchangeably?

Interchangeability allows the MDM to use either Legacy Tyvek® or Transition Tyvek® for devices already on the market, provided that:

- The MDM has considered this in their change control, risk management and regulatory submission processes.
- The specifications for the device package do not restrict the use of Legacy Tyvek® or Transition Tyvek®.
- There were no changes to the packaging or sterilization process conditions.
- Any required regulatory submissions for the transition are structured and approved to allow both products to be used (if applicable).

5. How does DuPont communicate MPTP test results for specific material combinations?

All documents are posted at www.areyouready.tyvek.com. The Package Test Results Selector Tool allows you to download results for specific categories of packaging types and sterilization methods.

6. What do I need to do from a regulatory standpoint if my device falls outside the Transition Protocol?

If your device is outside the scope of study performed in the U.S. FDA Transition Protocol (for example, you are using a completely different sterilization modality, such as chlorine dioxide), please refer to the specific guidance from the U.S. FDA, Health Canada, or your notified body posted at www.areyouready.tyvek.com for guidance.

7.How long will the website www.areyouready.tyvek.com with the data and links be available to the industry?

Documents on the www.areyouready.tyvek.com website will be available through 5-Year Real-Time Aging (2019).

8. There is a very large amount of documentation available on the Are You Ready? website; where should I start for my change assessment?

As a start, MDMs may consider to review the following documents, leading to many of the other documents as needed:

- Industry Executive Summary Report
- MPTP Materials List
- Package Test Results Selector Tool
- Cell Descriptors
- Risk Assessment Building Blocks
- MPTP Styles 1073B and 1059B Compliance to EN ISO 11607
- Medical Packaging Reference Library (check the Regulatory section for the regulatory letter and certificates)

MDMs should also consult the Regulatory Guidance section and review the documents for your specific country or region, if available.

9. Who can I talk to if I have more questions?

We have DuPont experts available in all regions to answer your questions. You can find contact information on our website.

REGULATORY

10. What guidance did the U.S. FDA provide?

We engaged the Center for Devices and Radiological Health (CDRH) at the U.S. FDA to help mitigate regulatory requalification. CDRH provided input to the Transition Protocol design. Over the course of the protocol, CDRH reviewed extensive data analysis by DuPont of independent third-party generated data to show that Tyvek® produced as a result of the transition does not represent a significant change in functional performance compared to Legacy Tyvek®.

On October 1, 2015, CDRH published a letter to confirm their conclusion of functional equivalence of Transition Tyvek® to Legacy Tyvek® providing the following guidance:

> "...it is not necessary, absent a specific request or notice from FDA or a risk analysis finding to the contrary, for medical device manufacturers to submit a new 510(k) or PMA supplement for a change solely in packaging from the Legacy Tyvek® to the Transition Tyvek® manufactured using an upgraded spinning process."

The letter also includes essential steps to be completed with the implementation of Transition Tyvek® in accordance with FDA's medical device Quality System Regulation. A copy of this letter is posted on our website at www.areyouready.tyvek.com in the regulatory section

11. What guidance have you received from European Notified Bodies?

In Europe, five Notified Bodies: BSI Assurance UK Ltd, LNE/G-MED, SGS United Kingdom Limited, TÜV Rheinland LGA Products GmbH and TÜV SÜD Product Service GmbH issued guidance letters for European compliance which are posted on our website. These five Notified Bodies received a copy of the U.S. FDA Transition Protocol Amendments and no issues have been reported.

In addition, AMTAC Certification Services Ltd and Intertek SEMKO AB, DQS Medizinprodukte GmbH, NSAI Inc., DEKRA Certification B.V. and DEKRA Certification GmbH have issued position statements of which some are posted on the MPTP website.

Several Notified Bodies have made guidance available to their clients. It is recommended to contact notified bodies and to read their guidance to meet requirements for successful submission.

12. What guidance have you received from Japan?

In Japan, a three-party meeting was held on September 25, 2013, with the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceutical and Medical Device Agency (PMDA); the Association of Registered Certification Bodies (ARCB) under PAL; and the Japan Federation of Medical Device Association (JFMDA). Specification and miscellaneous properties of Transition Tyvek® were reviewed during the meeting. The September 25, 2013, Guidance was to file a Minor Change Notification Form (Keibi Henkou Todoke); however, laws have changed. Based upon new laws, NO ACTION IS REQUIRED. A translation of the June 1, 2015, Guidance is available on our website at www.areyouready.tyvek.com in the Regulatory Guidance section. If you file a Minor Change Notification Form (Keibi Henkou Todoke) for another reason, delete the references to sterile packaging material.

13. What guidance have you received from China?

In China, we are working with the China Food and Drug Administration (CFDA) Jinan Quality Supervision and Inspection Center for Medical Devices. CFDA-Jinan performed material property testing on current product as part one of a two-part study. In part two, they repeated the testing using Transition Tyvek® and control materials. Testing included: basis weight; Mullen burst; delamination; hydrostatic head; Gurley Hill porosity; microbial barrier; and tensile strength. Criteria were previously established for determining Functional Equivalence of specification and miscellaneous properties. A final report with results of Functional Equivalence was issued by CFDA-Jinan in December 2013. The report states: "For the DuPont™ Tyvek® products manufactured with DuPont's latest flash spinning technology and current manufactured DuPont™ Tyvek® products, all the testing results meet the criteria of functional equivalence and non-inferiority under the DuPont Validation Protocol." An English translation of the report was issued by CFDA-Jinan in March 2014; a summary is posted on our website.

14. What guidance have you received from Health Canada?

Individualized letters were sent by Health Canada on September 30, 2015, to the regulatory contacts for all current Class III and IV Medical Device License Holders describing the Action Required. A copy of the letter and the two attached forms are posted on our website at www.areyouready.tyvek.com in the Regulatory Guidance section. The two forms in this communication—September 30, 2015, License Notification and the Attestation Page—must be completed and signed by a senior official of the device manufacturer and returned by December 31, 2015. The assessments must be documented in the device manufacturer's quality management system. Depending upon the responses in the returned form, additional actions may be necessary.

15. Where can I find more regulatory information on MPTP?

www.areyouready.tyvek.com

TECHNICAL

16. The conditions for testing the effects of steam sterilization were 127°C for 30 minutes. What could effects be on Transition Tyvek® after longer exposure time?

We are testing longer exposures. See the MPTP Cell Descriptor Selector Tool on our website for details on this as well as an overview of all package configurations and constructions that are being tested.

17. Will you perform longer-term aging studies as part of the Transition Protocol?

In the Phantom Protocol we are generating 7- and 10-year accelerated aging data and 10-year real-time aging data for some cells containing devices that have these extended expiry dates.

18. What about Pharmacopeia and Food Contact Regulations?

While not an official part of the Transition Protocol, Tyvek® 1073B and Tyvek® 1059B produced on the newer assets will be Pharmacopeia and Food Contact compliant by meeting extractable testing and compositional requirements, as are Tyvek® 1073B and Tyvek® 1059B manufactured on the original lines. Test data required to meet these regulatory requirements was generated as part of Biocompatibility, Food Contact and Pharmacopeia Testing. Results can be found on our website.

19. Are all line/polymer combinations represented by the specification and miscellaneous properties published for Transition Tyvek®?

Yes, all line/polymer combinations are represented.

20. We approve our validations to 3X EO cycles. Is it possible to perform 3X EO sterilization cycles on Transition Tyvek®?

There are several examples of package configurations being tested in the MPTP that are sterilized by 3X ethylene oxide (EO) cycles. Please reference the MPTP Cell Descriptor Selector Tool found on our website.

21. Do you compare the mechanical strength of Transition Tyvek® vs. Legacy Tyvek®?

We have posted physical and mechanical property data for Transition Tyvek®, and a data sheet showing a comparison of the key properties of Legacy Tyvek® vs. Transition Tyvek®, on our website.

22. What types of printing processes were tested on Transition Tyvek®?

Two printing technologies commonly used in the medical packaging industry—flexography and thermal transfer—have been assessed. Results of the printing trials are posted on our website. It is also important to note that SPMs and MDMs participating in the MPTP have successfully printed Transition Tyvek® using existing printing equipment and process conditions with no issues observed or reported.

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23. Do MDMs need to do their own testing for configurations not covered in the Transition Protocol or the Phantom Protocol?

The intent of the MPTP is not to capture every possible material combination and sterilization method, but rather to show a broad cross-section of materials and sterilization methods used in the industry and prove the material produced using the latest flash-spinning technology is functionally equivalent to the Legacy product. It's not practical to test every possible combination and sterilization method, which is why DuPont is using the principle of Functional Equivalence as the basis for this project.

24. When did DuPont issue a formal change notification for the Transition?

In 1Q 2014 we issued a formal Change Notification letter for DuPont™ Tyvek® 1073B and Tyvek® 1059B to all customers who have a Change Notification Agreement in place with DuPont.

Remember, www.areyouready.tyvek.com is the repository of ALL MPTP information. Investing time to review what is already available may be a large cost savings in your review process.