

DUPONT™ TYVEK® 1073B AND TYVEK® 1059B TRANSITION PROTOCOL FAQs—JUNE 28, 2011

1. Why is DuPont making this transition?

DuPont will be transitioning Tyvek® 1073B and Tyvek® 1059B to manufacturing lines that use our latest flash-spinning technology to meet growing future demand, particularly as the world's aging population increases and access to quality medical care improves in developing nations, and to help ensure the continuity and flexibility of future supply.

2. Will Tyvek® Asuron™ and Tyvek® 2FS™ be part of this transition?

No. Tyvek® Asuron™ and Tyvek® 2FS™ were commercialized on manufacturing lines that already use our latest flash-spinning technology, and, therefore, will not be part of the transition.

3. What is the transition protocol?

The transition protocol is a plan developed to transition Tyvek® 1073B and Tyvek® 1059B from the current to the latest flash-spinning technology and equipment. Based on sound principles of design and statistical analysis, the transition protocol is a systematic method for generating data to prove that the Tyvek® produced with the latest flash-spinning technology is functionally equivalent in performance to the Tyvek® you use today. This plan has been reviewed and accepted by the Center for Devices and Radiological Health (CDRH) at the U.S. FDA.

4. What does functionally equivalent mean?

Functionally equivalent means that the attribute you are measuring may be different, maybe even statistically, but it still meets functional and performance requirements. The goal of the transition is to produce material that performs the same in your processes and applications as the Tyvek® you are using today.

5. What role does the U.S. FDA play in this transition?

DuPont reviewed the protocol with the U.S. FDA, which provided input and approved it in 2011. Over the course of the protocol implementation, the U.S. FDA will review 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 the Tyvek® currently being used. If the U.S. FDA agrees with DuPont's analysis and conclusions, then it would issue guidance indicating that medical device manufacturers (MDMs) would not be required to file amended 510(k)s or PMAs for existing devices because the transition represents a merge, or lot, change.

6. Will governing or regulatory authorities outside the United States accept the position of the U.S. FDA and issue similar guidance?

We have shared our transition plan with global authorities, including: the Japanese Ministry of Health, Labour and Welfare; select European Notified Bodies; and the Chinese State Food and Drug Administration. We are continuing discussions with these agencies and taking action as appropriate. We anticipate they will take the same position as the U.S. FDA.

7. Will Tyvek® manufactured using the latest flash-spinning technology perform in the same way as the Tyvek® I am currently using?

The objective of the development phases and the transition protocol itself is to demonstrate functional equivalence to the Tyvek® you are currently using in terms of seal strength, microbial barrier and package integrity.

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8. What could be different about Tyvek® manufactured using the latest flash-spinning technology compared to the Tyvek® I use today?

The goal of the protocol is to produce material that performs the same in your processes and applications as the Tyvek® you are using today. Initial observations show potential product improvements may be possible but these need to be confirmed and validated.

9. When will Tyvek® 1073B and Tyvek® 1059B manufactured using the latest flash-spinning technology be commercialized?

We expect product to be commercially available by late 2012 for new devices and in 2014 for existing devices.

10. Will there be any differences in the polymer used?

All polymers will continue to be virgin high-density polyethylene (HDPE) that will meet U.S. and European pharmacopeia regulatory compliance. The HDPE being used was selected for specific attributes required to produce functionally equivalent Tyvek® product.

11. How can I stay up to date with this ongoing process?

To help you stay informed throughout the transition process, we have created a special section on our website (www.MedicalPackaging.DuPont.com) where you'll be able to find the latest transition information, such as when key milestones are reached. And, because we understand how critical timely communications are to the success of your business, we will be making announcements well in advance about any actions that your organization may be required to make.

12. Combination products and pharmaceutical applications have different requirements. How will you support those?

We will test a representative sample to prove functional equivalence and consider other requests on a case-by-case basis. During the development phases, we are trying to capture all key applications for prove-out testing.

13. What will happen to the current manufacturing lines that you're using to manufacture Tyvek® 1073B and Tyvek® 1059B?

Our goal is to transition medical styles to our latest manufacturing technology upon receipt of the U.S. FDA letter confirming functional equivalence.

14. For inventory purposes, how will I be able to differentiate Tyvek® manufactured on the old versus newer equipment?

Specific product identifiers will enable tracking of production sources and be communicated prior to commercializing the new products.

15. Do you envision any potential product performance enhancements for Tyvek® manufactured on the newer equipment?

Initial observations show potential product improvements may be possible but these need to be confirmed and validated.

DUPONT™ TYVEK® 1073B AND TYVEK® 1059B TRANSITION PROTOCOL FAQs**JUNE 28, 2011****16. If an MDM has multiple suppliers of a package, will DuPont test all of them?**

No. A representative configuration will be selected and tested.

17. Is distribution testing included in the protocol?

Distribution testing was removed from the protocol because the only package failures that were seen in the initial study were the result of shipping carton failure in the drop test. Transportation testing is a challenge to the materials of construction, the package design and the protective packaging. The protocol is focused on the sterile barrier system.

18. Which MDMs will be included in the project and how and when will they be selected?

We have been working with sterile packaging manufacturers (SPMs) and a “beta” group of MDMs in the initial stages of this project to test candidate material and gain valuable “voice of the customer” information. We will continue to work with SPMs and MDMs to complete the matrix. This work is ongoing and our intention is to have the selection process completed by the end of 2011. After all of the protocol testing matrix cells are filled, the matrix will be representative of the materials and packaging configurations used by the global medical device market.

19. If I am not currently in the representative group of MDMs involved in protocol testing, can I volunteer to be?

DuPont will consider additional MDM involvement required to meet protocol testing needs on a case-by-case basis.

20. Can I get access to developmental materials to do my own testing?

No. We will not be able to supply every SPM and MDM with material during this time because we will have limited supply which will be used first to complete the protocol testing.

21. After the transition, will I be able to get the same Tyvek® that I currently purchase?

No. The goal of transitioning Tyvek® 1073B and Tyvek® 1059B to our latest flash-spinning technology is to provide Tyvek® that is functionally equivalent to the Tyvek® you use now. After the transition, the material produced on the older manufacturing lines will not be available for purchase for use in medical packaging applications.

22. Will the style names change? And, if not, how can I track the difference for inventory purposes?

Material from the newer lines will have specific identifiers to enable you to track the styles manufactured on the newer lines versus current Tyvek® prior to full commercialization.

23. In the protocol testing matrix, why isn't steam sterilization or vapor hydrogen peroxide included?

The official protocol is focused on the most commonly used sterilization methods, which are ethylene oxide (EO), gamma irradiation and electron beam. Outside of the protocol, we will be working directly with MDMs and pharmaceutical companies to conduct evaluations with other sterilization methods.

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24. Why is DuPont making this announcement in 2011 when the transition period for most MDMs will take place in 2014 and 2015?

This is truly a collaborative effort involving DuPont, SPMs, MDMs and regulatory authorities around the world. We are communicating now to finalize participants in each “cell” of the protocol by the end of 2011 so that we can prepare for generating packages for the protocol in 2012. In addition, we believe that it is important for everyone in the industry to be informed throughout the various phases of this transition process.

25. Can I see an actual copy of the protocol submitted to the U.S. FDA?

This document contains DuPont proprietary information so we will not be making this publicly available. We will make details of the protocol available to companies participating in the study under confidentiality agreements.

26. What data will be available before MDMs start package creation for the protocol?

We will have select physical properties, cytotoxicity and accelerated aging testing completed before the protocol is initiated.

27. What data will be available after the completion of the protocol testing? Will it be Tyvek® data or packaging data?

Following completion of the transition protocol testing at a third-party laboratory, we will have data available for Tyvek® material and packaging data for pre-sterilization, post-sterilization and post-sterilization under accelerated and real-time aging conditions. We are considering creating a general data report that would be available to the industry—but which would not compromise individual company’s confidential information.

28. Why are there very few packages made with Tyvek® 1059B included in the protocol?

Tyvek® 1073B is used in more widespread applications globally and enables complete protocol matrix fulfillment. The protocol packages utilizing Tyvek® 1059B are demanding applications that will demonstrate the functional equivalence of Tyvek® 1059B. More widespread testing of Tyvek® 1059B is being conducted during the product development phase.

29. Why are you only testing uncoated Tyvek® 1059B and not coated Tyvek® 1059B?

The most demanding application for Tyvek® 1059B is uncoated. The effects of coating will be shown through the testing of Tyvek® 1073B.

30. In the protocol testing matrix, there are only 60 different devices. How will this be reflective of all the different packages that are possible?

When you look at all the types of packages that exist, they fall into three basic categories: pouches & header bags; form-fill-seal applications; and rigid trays & lids. Because every protocol package fits into one of these three categories, we are testing a representative cross section of materials, package designs and manufacturers. It would be impossible and cost prohibitive to test every bottom web material used in the industry.