



# Tyvek® 1421B

for in-process pharmaceutical applications



DuPont™ Tyvek® products are available for a wide variety of applications across diverse industries, specifically designed and manufactured for their intended use. There are several styles of Tyvek® for healthcare packaging— Tyvek® 1073B, Tyvek® 1059B and Tyvek® 2FS™— each with their own technical specifications.

Tyvek® 1421B is specifically developed for in-process pharmaceutical applications to protect surfaces of cleanroom equipment, components and accessories from particle and microbial contamination. Made from HDPE using DuPont proprietary flash-spinning technology, Tyvek® 1421B is softer and more fabric-like compared to other healthcare packaging styles of Tyvek® used in sterile packaging. This makes Tyvek® 1421B ideal for pharmaceutical cleanroom and controlled environment covers and bags. Typical product examples include cleanroom equipment covers, stopper bowl covers, sterilization wrapping and autoclave component bags and covers.

Manufacturing processes for pharmaceutical products require strict quality practices. These requirements will further increase with the introduction of the revised European Good Manufacturing Practice (EU GMP) Annex 1 that describes principles applied for manufacture of sterile products. Special focus is on the systematic implementation of quality risk management (QRM) to ensure prevention of microbial and particulate contamination in the final product. Anticipating these GMP changes, the recently published ISO/DIS 13408-1 provides guidance on how to manage quality risks and on developing an adequate contamination control strategy for aseptic processing of healthcare products.

## Key highlights

- Minimizes the risk of particle contamination in cleanrooms and controlled environments
- Provides sterility assurance with trusted microbial barrier performance of Tyvek®
- Supports regulatory compliance of pharmaceutical processing (e.g., GMP Annex 1)
- Resists tears and punctures
- Fabric drapability supports various designs
- Breathability helps to minimize the formation of condensation in steam sterilization
- Certified 100% recyclable\*



\*Tyvek® is made of HDPE and products made of 100% Tyvek® material can be recycled at facilities that recycle flexible HDPE materials. Please check recycling facilities in your area to ensure they can recycle Tyvek®.

In-process pharmaceutical coverings made of Tyvek® 1421B support manufacturers in establishing efficient production and safe sterilization processes. When working in an aseptic processing environment, minimizing the risks of particle contamination is critical. Consisting of continuous and interconnected fine HDPE filaments, Tyvek® 1421B helps minimize the risk of particle or microbial contamination of the pharmaceutical products or materials being handled.

The porous nature of Tyvek® 1421B makes it highly breathable, which is essential for effective steam sterilization cycles and to minimize the formation of condensation. Material durability and drapability facilitate various product designs while high tear and puncture resistance provide additional security against punctures from sharp edges. For developing a steam sterilization cycle for covers made with Tyvek® 1421B, please consult manufacturers of covers.



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