PROVEN SOLUTIONS FOR PHARMACEUTICAL PROTECTION
DuPont™ Tyvek® provides trusted protection every step of the way

Pharmaceutical products help improve and save lives around the world every minute of every day.

Critical to the health and well-being of people everywhere, pharmaceutical products require the highest level of protection during every step of the process—from manufacturing until point of use. The safety of these products cannot be left to chance. Nor can the safety of the operators who are exposed to high potent active pharmaceutical ingredients (HPAPI).

That’s why leading pharmaceutical manufacturers around the world rely on DuPont™ Tyvek® to provide trusted protection during aseptic processing, for active packaging for desiccants, for sterile barrier systems, for final product packaging and for temperature protection during shipment.

Since its introduction in 1967, Tyvek® has enabled new dimensions of protection, security and safety in a wide variety of industries and applications. One of the first commercial applications for this innovative material was healthcare packaging, an industry where it quickly earned recognition as a standard of excellence, providing the trusted protection patients and healthcare providers need to accomplish bigger things.

The unique structure of Tyvek®—tough, continuous filaments—creates both a tortuous path for superior microbial barrier and excellent strength properties. Made of high-density polyethylene (HDPE), Tyvek® has a unique balance of properties, which cannot be found in any other material.

Specifically, Tyvek® is lightweight, yet strong, vapor-permeable, yet moisture- and chemical-resistant; as well as puncture-, tear- and abrasion-resistant. Tyvek® is also low-linting, smooth and opaque. It is compatible with the most commonly used sterilization modalities, including: ethylene oxide (EO), gamma, electron-beam, steam (under controlled conditions) and low-temperature oxidative sterilization processes, such as vaporized hydrogen peroxide (VHP). And, Tyvek® offers the benefit of high material safety.

For nearly 50 years, Tyvek®—the material For Greater Good™—has been helping to protect the health of millions of patients worldwide by providing trusted protection for pharmaceutical products and medical devices.

When pharmaceutical products are protected by Tyvek®, pharmaceutical manufacturers can worry less about potential contamination or damage to their products so they can focus on healing the sick and helping healthy people stay healthy.
Offering an ideal balance of protection, durability, comfort and contamination control, DuPont Tyvek® garments not only protect pharmaceutical products and processes from contamination, they also protect the operators working in cleanrooms and other controlled environments from potential exposure to hazardous substances.

Designed especially for use in cleanrooms and controlled environments demanding high levels of microbiological protection, sterile Tyvek® IsoClean® coveralls are suitable for cleanrooms up to GMP A&B, ISO 4/5 and CLASS 10/100 controlled environments.

Tyvek® IsoClean® garments are available in a wide variety of styles, such as coveralls, hoods and boot covers, enabling protection from head to toe.

Featuring the lowest linting and particle shedding of any garments in the DuPont portfolio, Tyvek® IsoClean® single-use garments offer consistent protection performance—every time—and help make both your inventory and cost more predictable.

For wearer and aseptic process, DuPont™ Tyvek® garments provide trusted protection

In addition, Tyvek® IsoClean® sterile garments:

- Feature typical bacterial filtration efficiency of 98.4% (for the CS option, as measured by ASTM F2101)
- Have a sterility assurance level (SAL) of 10^-6; irradiation dose is validated in accordance with ANSI/AAMI/ISO 11137 through bioburden and dose verification testing
- Are gamma irradiated in a facility that is registered by ISO 13485 and adheres to the requirements of ANSI/AAMI/ISO 11137
- Come with a Certificate of Sterility and a Certificate of Compliance
- Are specially processed to minimize particle shedding, then folded for aseptic donning and individually packed
- Tyvek® IsoClean® IC 183 DS is available as Category II personal protective equipment (PPE) and CE certified

Tyvek® 600 Plus coverall offers the added benefit of protective design features and overlapped seams. It helps provide an effective barrier against many water-based inorganic chemicals in low concentration, small-sized hazardous particles and biological hazards. This coverall is ideal for applications within the pharmaceutical manufacturing sector that require effective whole suit protection offered by a Type 4 suit because it protects wearers from hazards such as liquid aerosols, liquid splashes or toxic airborne solid particulates.

Specially designed for use in laboratories and in the pharmaceutical industry, Tyvek® 500 Labo coverall acts as a barrier that helps protect both the wearer—when exposed to water-based inorganic chemicals and fine particles—and the process, from contamination by the wearer. This makes it ideal for use during the production and handling of products such as pharmaceuticals, cosmetics and optical and electronic devices.
Packaging made with DuPont™ Tyvek® 1073B, a strong, low-linting material, enables sterilization and protection of parts for sterile pharmaceutical processing and helps protect final products, such as pre-filled syringes or combination products. Tyvek® 1073B is also an ideal material for use in product and processing concepts in cleanroom environments for aseptic processing.

With its unparalleled balance of properties, Tyvek® 1073B delivers trusted protection for a wide range of pharmaceutical packaging applications, helping pharmaceutical manufacturers around the world to:

- Enable sterilization and protection of parts for sterile pharmaceutical processing
- Ensure sterility maintenance of components such as closures, stoppers and pre-fillable containers prior to entering your sterile manufacturing areas
- Provide a high degree of protection for packaged and sterilized drug and device combination products such as drug-coated stents
- Enable the outside surface sterilization of a primary packaged (combination) device that cannot be sterilized itself (e.g., through low-temperature VHP sterilization)
- Enhance the presentation and ease-of-use of sterile and non-sterile products in peel pouches, sterilization bags, port bags, header bags, nested container systems and flexible or rigid tray configurations

When you choose Tyvek® 1073B, you can rest assured that you have chosen a material that supports long-term use of validated pharmaceutical packaging solutions. Since Tyvek® 1073B was commercialized in 1972, the manufacturing process and polymer source for this material have only been changed once—as part of the Tyvek® Medical Packaging Transition Project (MPTP).

Benefits of Tyvek® 1073B for pharmaceutical packaging and aseptic processing applications

- Clean environments thanks to low-linting features
- Compliance with rigorous international standards, including pharmacopeia regulations
- Long-term sterility maintenance due to outstanding microbial barrier
- Optimal protection due to excellent tear strength and puncture resistance
- Sterilization compatibility
Active packaging made with DuPont™ Tyvek® 1073B and Tyvek® 1059B helps protect pharmaceutical products by providing three critical benefits:

• Best-in-class absorption—due to high gas permeability of Tyvek®
• No contamination risk—due to efficient barrier and excellent strength of Tyvek®
• Fully compliant solution—because Tyvek® 1073B and Tyvek® 1059B meet testing requirements of USP <661.1>; European Pharmacopoeia 3.1.3 and 3.1.5; and EU and US Food Contact Regulations*

Choosing Tyvek® 1073B and Tyvek® 1059B will maximize the protective benefits of active packaging for your pharmaceutical applications and can lead to ease of processing in your facility.

Tyvek® 1073B and Tyvek® 1059B are ideal for use as desiccants for packaged pharmaceutical products, providing critical protection and efficacy. The unique properties of Tyvek® allow vapor to enter but keep water droplets out, providing best-in-class absorption. When used as lyophilization and culture bags, active packaging made with Tyvek® provides an effective barrier to particles and contamination. What’s more, the high permeability of Tyvek® leads to ease of processing.

*Additional information available upon request.
DuPont™ Tyvek® Cargo Covers provide vital thermal protection during short-term storage and distribution of temperature-sensitive pharmaceutical products. They are available in three types—Tyvek® Solar W10, Tyvek® Solar W20 and Tyvek® Xtreme W50—and a wide range of industry-standard and customizable sizes.

Tyvek® Cargo Covers are designed to provide a reliable and affordable means of protecting pharmaceutical shipments that must be kept within common controlled room temperature (CRT) bands in accordance with prevailing regulations. Tyvek® Xtreme W50 can also be used as a stand-alone barrier in CRT categories where there is a need for protection against cold as well as hot conditions.

Tyvek® Cargo Covers protect the physical and clinical integrity of pharmaceutical products in transit by:
• Significantly reducing the risk from external environmental variables such as solar radiation, excessive ambient temperatures, low temperature dips and humidity swings
• Speeding recovery to desired target temperature when brought back into the cold chain from a hot environment exposure
• Allowing the controlled escape of condensation and excessive moisture, minimizing the risk of water damage to product, packaging and labels
• Providing extreme water resistance, even when subjected to prolonged sun and 50-mph wind-driven rain
• Offering a highly effective barrier against dust, pollen, bird droppings, insects, rodents, odors and other sources of contamination
• Featuring an opaque outer surface that provides security from prying eyes and makes it easy to detect tampering

Specifying Tyvek® Cargo Covers to protect your temperature-sensitive pharmaceutical products during transport can free you from worrying about the physical hazards of cold chains so you can focus on what you do best—providing products that help improve and save lives around the world.
For more information about how DuPont® Tyvek® can help meet your pharmaceutical protection needs, visit pharmaprotection.dupont.com