

DUPONT™ TYVEK® ISOCLEAN®

FREQUENTLY ASKED QUESTIONS

What is Tyvek®?

Tyvek® is a flashspun high-density polyethylene fabric only made by DuPont. Tyvek® fabric offers an inherent, breathable barrier that cannot easily be worn or abraded away. This inherent barrier of Tyvek® is not dependent on a thin film or a thin layer of small fibers - with Tyvek®, every part of the fabric provides barrier. This delivers an effective breathable barrier to particles due to the torturous path created by this unique fabric structure.

What class cleanrooms are Tyvek® IsoClean® garments suitable for?

Tyvek® IsoClean® (Option Code CS, DS and MS) garments are most typically considered for use in GMP A-D, ISO Class 5-8 (former Federal Standard 209E classes 100–100,000) cleanroom environments. However, use in ISO Class 4 and 9 environments may also be considered depending on the needs of a particular application. In all cases, garment choice depends on evaluation of, among other attributes, garment design and processing, as well as the needs of specific applications. Clean processed and bound seam garments offer the highest level of contamination control and should be used in more critical applications. Sterile garments are available if required. It is the end-user's responsibility to determine the appropriate garment for a given application.

How are garments for controlled environments processed and packed?

Non-Sterile garments are available in:

- **Bulk (option code 0B or 00):** Case quantities are packed in a cardboard case with two polyethylene liners.

Sterile Garments are available in:

- **Clean-Processed and Sterile (Option Code CS, DS and MS):** Garments are specially processed to minimize particle shedding, then folded to aid aseptic donning and individually packed in an ISO Class 4 cleanroom. The case quantity is packed in a cardboard case with two polyethylene liners. Sterility is achieved by gamma irradiation. Irradiation dosage is validated in accordance with ISO 11137 for a sterility assurance level (SAL) of 10⁻⁶. All DuPont™ Tyvek® IsoClean® clean-processed and sterile accessories (option code MS and DS) are packed in a dual barrier validated packaging system, consisting of an inner and outer easy tear, validated, cleanroom bag. The system serves both as an additional sterility risk management component and is a key element for contamination risk reduction when transferring apparel into clean areas.
- **Sterile (Option code 0S):** Garments are folded to aid aseptic donning and individually packed. The case quantity is packed

in a cardboard case with two polyethylene liners. Some sterile items are folded and individually packed in an ISO Class 5 cleanroom. Sterility is achieved by gamma irradiation. Irradiation dosage is validated in accordance with ISO 11137 for a sterility assurance level (SAL) of 10⁻⁶.

What is the expiration date of sterile garments?

Sterile items are generally considered to remain sterile as long as the package integrity has not been compromised (no breach of package or seals). Aging studies indicate that Tyvek® IsoClean® garments have a sterility expiration date of at least 5 years when stored in original packaging under proper storage conditions. For sterile Tyvek® IsoClean® products, the product expiration date is located on the bag and box label. DuPont suggests that non-sterile Tyvek® IsoClean® garments be used within 5 years of receipt.

Are certificates of sterility available for Tyvek® IsoClean® garments?

A certificate of sterility is provided with each case of sterile garments. Copies of certificates of sterility are available at www.safespec.dupont.co.uk

Why do Tyvek® IsoClean® garments have an odour after gamma sterilization?

Tyvek® IsoClean® garments that have been sterilized using gamma radiation will sometimes exhibit an odour, particularly when the packaging is first opened. This odor is expected and very normal.

Are Tyvek® IsoClean® garments anti-static or static dissipative?

The fabric used to make Tyvek® IsoClean® garments is treated with a topical antistatic agent to help minimize static buildup and reduce nuisance garment cling. The topical antistat is water soluble, so antistatic performance is reduced in clean-processed garments. Sterilization may also impact anti-static performance.

In situations where static dissipation level is a critical performance property, end-users should evaluate the performance of their entire ensemble, as worn, including outer garments, inner garments, footwear and other personal protective equipment (PPE). In order for any garment system to be static dissipative, it must be able to drain a charge buildup through proper grounding devices, such as, but not limited to, workstation grounding clips or static-dissipative floors. Check for CE-certified Tyvek® IsoClean® garments that meet EN 1149-5.

How should Tyvek® IsoClean® garments be stored?

The coveralls may be stored between 15 and 25 °C in the dark (cardboard box) with no UV light exposure. DuPont suggests that Tyvek® IsoClean® coveralls be used within 5 years, provided they are properly stored and pass a full visual inspection. High temperature, oxidizing gases, wet, cold, ultraviolet and ionizing radiation can significantly impact the long-term life of coveralls made of Tyvek® fabric. For sterile products see expiry date on bag label.

Are Tyvek® IsoClean® garments offered in any other colors than traditional white?

Currently DuPont offers the Tyvek® IsoClean® brand of cleanroom garments only in white.

At what temperatures would Tyvek® melt?

Tyvek® fabric melts at 135 °C. Tyvek® and Tyvek® IsoClean® garments are not flame resistant or flame retardant. Garments should not be used around heat, flame, or sparks.

Are Tyvek® IsoClean® garments water repellent?

Tyvek® IsoClean® brand garments offer limited splash protection, resist water penetration, are nonabsorbent, and have equal strength wet or dry. Tyvek® IsoClean® garments are not recommended for protection from liquid hazardous chemicals; if protection from liquid hazardous chemicals is needed, consider the DuPont™ Tychem® products available at www.safespec.dupont.co.uk

How can Tyvek® garments be disposed of?

Tyvek® coveralls can be incinerated or buried in a controlled landfill without harming the environment. Disposal of contaminated garments is regulated by national or local laws.

Can garments made of Tyvek® be recycled?

Yes, non-contaminated garments used in cleanroom operations can be recycled for non-hazardous applications.

This information is based upon technical data that DuPont believes to be reliable. It is subject to revision as additional knowledge and experience are gained. DuPont makes no guarantee of results and assumes no obligation or liability in connection with this information. It is the user's responsibility to determine the nature and level of hazards and the proper personal protective equipment needed. The information set forth herein reflects laboratory performance of fabrics, not complete garments, under controlled conditions. It is intended for information use by persons having technical skill for evaluation under their specific end-use conditions, at their own discretion and risk. Anyone intending to use this information should first verify that the garment selected is suitable for the intended use. In many cases, seams and closures have shorter breakthrough times and higher penetration rates than the fabric. Please contact DuPont for specific data. These garments are intended for limited use and should be disposed of after single use. If fabric becomes torn, abraded or punctured, or if seams or closures fail, or if attached gloves, visors, etc. are damaged, end user should discontinue use of garment to avoid potential exposure.



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