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.SafeSpecCleanroom.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. Under certain conditions, such as cold and dry weather, it is possible that garments might build and discharge static electricity. Discharges are

not normally dangerous except in situations where the generation of an electrical spark could ignite a flammable atmosphere or startle the wearer. When operating around flammable chemicals, take steps to eliminate potential static discharges. In these situations, suggested steps include, but are not limited to, water spray, the use of an overcover, raising humidity level of the work area, use of a commercial anti-static application coating, grounding straps on equipment and personnel, inherently static-dissipating under- and over-garments, and testing of the worker's static dissipation before entry into the classified area.

However, in the case of explosive or flammable atmospheres, even if steps are taken to manage static formation and dissipate static charge, the risk of severe injury remains if an uncontrolled or accidental ignition occurs. Do not wear Tyvek® protective garments in potentially flammable or explosive atmospheres. Do not knowingly enter an environment in which the concentration of flammable gas is within flammable or explosive limits while wearing a Tyvek® garment. If you determine that you are in a potentially flammable or explosive environment, retreat immediately.

How should Tyvek® IsoClean® garments be stored?

Store Tyvek® IsoClean® garments in a cool, dark, dry location free of dirt and insects. Sunlight, ozone, high temperatures (>49 °C; 120 °F), vehicle exhaust fumes, compression under heavy weights, and sharp edges or projections are some conditions known to degrade the materials in these garments. These factors should be considered when evaluating the long term life of storage of Tyvek® and Tyvek® IsoClean® garments.

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 (275 °F). Tyvek® and Tyvek® IsoClean® garments are not flame resistant or flame retardant. Garments should not be used around heat, flame, sparks, or in potentially flammable or explosive environments.

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.SafeSpecCleanroom.dupont.co.uk**

How can Tyvek® garments be disposed of?

Tyvek® garments, if not contaminated, may be landfilled or incinerated in accordance with local regulations. Uncontaminated chemical protective garments may be incinerated in a facility that is capable of handling mixtures containing plastics. Likewise, an uncontaminated chemical protective garment may be buried in a facility that accepts plastic materials.

Contaminated garments that cannot be handled safely without protective equipment must be disposed of with other hazardous wastes, either through incineration or landfill, per local regulations.

Can garments made of Tyvek® be recycled?

Yes, non-contaminated garments used in cleanroom operations can be recycled for non-hazardous applications.
For more information visit our webiste www.ipp.dupont.com

DuPont™ SafeSPEC™
www.SafeSpecCleanroom.dupont.co.uk