

DUPONT CONTROLLED ENVIRONMENTS

PRODUCT CATALOGUE



Contact.



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Introduction

Quality, comfort, durability and contamination control for your cleanroom

For more than 200 years, DuPont has been putting science to work by creating sustainable solutions essential to a better, safer, healthier life for people everywhere. One of the areas in which safety and health are of paramount importance is in cleanrooms and controlled environments.

DuPont understands your need to do everything possible to improve productivity and reduce risk in your controlled environment. The DuPont Controlled Environments portfolio offers a comprehensive selection of single-use cleanroom garments and accessories designed for use in pharmaceutical, medical device, biotech and electronic settings that require high standards for particle and microbiological contamination control.

Indeed, DuPont™ Tyvek® garments have a long history of use in cleanrooms due to their excellent barrier to particles, microorganisms and non-hazardous liquids. They offer an ideal balance of protection, durability, comfort and contamination control. They are available in many styles for different cleanroom and controlled environment applications, and are packaged and certified to meet local market requirements.

With the DuPont Controlled Environments offering, you get the advantage of a wide range of proven, science-based solutions that help keep your cleanroom environment protected.

For more information please visit tyvek.co.uk/isoclean



Introduction

DuPont™ Tyvek® garment material

The highest performing garments in our product line are made from DuPont™ Tyvek®, which has been used to make high-quality cleanroom garments for more than 20 years. Tyvek® is made by DuPont with a proprietary flash-spinning process that creates continuous fibers of high-density polyethylene that are randomly distributed and non-directional.

- Tyvek® is tough, yet lightweight and soft.
- Tyvek® offers an ideal balance of protection, durability, comfort and contamination control.
- Tyvek® acts as a breathable barrier against particles and bacteria.
- Tyvek® repels aqueous liquids and liquid aerosols.
- · Tyvek® is inherently low linting and abrasion resistant.

Picture 1: DuPont™ Tyvek® structure.



200x magnification Source: DuPont

DuPont quality systems for cleanroom garments

DuPont single-use garments for controlled environments offer the following standards of quality:

- ✓ The DuPont Controlled Environments quality management system is ISO 9001:2008 registered.
- ✓ DuPont™ Tyvek® IsoClean® sterile garments have a sterility assurance level (SAL) of 10⁻⁶. Radiation doses are validated in accordance with ANSI/AAMI/ ISO 11137 through bio burden and dose verification testing.
- ✓ DuPont[™] Tyvek[®] IsoClean[®] sterile garments are gamma irradiated in a facility that is registered by ISO 13485 quality standard and adheres to the requirements of ANSI/AAMI/ISO 11137.
- ✓ A Certificate of Sterility and a Certificate of Compliance come with every shipment of sterile Tyvek® IsoClean® single-use garments.
- ✓ Dose audits are conducted quarterly to maintain dose validation.

- Customers are invited to audit our manufacturing and sterilization facilities.
- Quality documentation is readily available and accurate when requested to help meet customer requirements.
- ✓ Lot traceability is maintained through garment manufacturing, processing and sterilization.
- ✓ All DuPont™ Tyvek® IsoClean® sterile products are packed in validated cleanroom sealed bags. Certain models are available 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.

Introduction

Ce-certified single-use garments from DuPont

DuPont clean-processed and sterile cleanroom garments, designed for single use, offer meaningful advantages in today's challenging cleanroom environments, including:

- ✓ Quality single-use garments are not subjected to multiple cycles of wearing, laundering and sterilization, so fabric barrier and strength are consistent and predictable. Also, DuPont Controlled Environments garments help minimize cross-contamination risk because clean-processing and packaging are done in a facility that only handles new garments.
- ✓ Flexibility the DuPont single-use apparel program allows you to order only the quantities that you plan to use, which offers flexibility as your needs change.
- ✓ Cost Control single-use garments help eliminate budget uncertainties associated with garment repair, damage and loss, helping you to better predict expenditures.

Category III chemical protective clothing

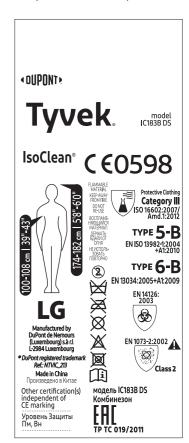
Selected DuPont™ Tyvek® IsoClean® garments are designed and manufactured to meet or exceed the European standards for Type 5 & 6 chemical protective clothing. They are CE marked as Category III PPE in accordance with the PPE Regulation (EU) 2016/425. Selected DuPont™ Tyvek® IsoClean® accessories (clean-processed and sterile, option code MS and a broad selection of the non-processed "bulk" items) are certified as either Category III or Category I PPE and, like garments, carry the CE marking. For MS items the CE certification and corresponding certified property performance claims are made on the garment product after clean-processing and sterilization.

To carry the CE mark, chemical protective clothing must:

- ✓ Meet the minimum requirements of the corresponding product standard which includes requirements on:
- Material and seam physical properties
- Chemical and particulate barrier properties of the material and whole garment
- Garment fit and labelling
- ✓ Hold a valid EC Type examination certificate (the "CE Certificate") from a 3rd party notified body
- ✓ Hold a valid Quality Surveillance contract / certificate
 with a 3rd party notified body

Tyvek® IsoClean® garments are certified as passing tests for compliance with both Type 5 (Protective clothing against airborne solid particulates) and Type 6 (Low level spray test). They have been additionally certified for protection against infective agents (EN 14126) and also meet the requirements of the ISO 16602 (Type 5 & 6) standard. See picture 2 for an example of the Tyvek® IsoClean® garment labelling.

Picture 2: Tyvek® IsoClean® product labelling.



2 Introduction

Introduction

Controlled environments apparel selection guide

When it comes to working in a broad range of controlled environments, specifiers have many product options from which to select. The process to understand which option matches a given environment can be confusing. DuPont has tried to help reduce some of that burden by providing a complete line of products and information to help guide specifiers through their selection process.

To get the most out of your cleanroom apparel, it is necessary to understand where each product can be used. To provide a quicker overview of our products and where they are intended for use, we developed the simple guide below. Our goal is to provide the appropriate DuPont product that is suitable for a given environment or hazard.

Table 1. Fabric performance features.

Fabric	Available Sterile	Particle Barrier	Non- Hazardous Liquid Barrier	Comfort	Durability	Static Dissipation †	Particle Shedding and Cleanliness	Strengths
DuPont™ Tyvek® IsoClean® flashspun polyolefin, clean-processed and sterile	Yes, Option code CS, MS and DS	•			•		•	Ideal
DuPont™ Tyvek® IsoClean® flashspun polyolefin, sterile	Yes, Sterile OS option	•	•	•	•	•	•	combination of protection, durability, comfort and
DuPont™ Tyvek® IsoClean® flashspun polyolefin, bulk		•		•	•	•		cleanliness.

Table 2. Cleanroom garments and accessories selection guide.

					T
		DuPo	nt™ Tyvek® Iso	oClean [®]	
	Environments/Hazards	Clean- Processed and Sterile (Option codes CS, MS and DS)	Sterile (Option code OS)	Bulk Non-Sterile (Option codes 00 and 0B)	Considerations
ents	GMP A&B, ISO 4/5, CLASS 10/100 controlled environments*	•			Tyvek® IsoClean® sterile garments offer excellent cleanliness, barrier and sterility assurance level.
Environments	GMP C&D, ISO 7/9, CLASS 10,000/ 100,000 controlled environments*			•	Tyvek® provides an inherent particle barrier and durability, and is low linting. Clean-processing and bound seams should be considered for more critical environments.
	Non-hazardous, dry particles	•	•	•	Tyvek® provides an inherent barrier against small particles. Bound seam garments offer a higher level of protection than serged seam garments.
Hazards	Hazardous powders Notice: DuPont Controlled Environments garments should not be used in potentially explosive or flammable environments.		•	•	Use bound seamed garments when working with hazardous powders.
	Hazardous liquid splash Examples: organic solvents, caustics				Please refer to our Tychem® product line for liquid and vapor chemical protection.
	Electric arc, industrial fire hazard, welding		Do Not Use		Please refer to Nomex® for flame-resistant apparel. Controlled Environment garments are not suitable for firefighting activities, nor for protection from hot liquids, steam, molten metals, welding, electric arc or thermal radiation.

Comparison within the DuPont portfolio:

Best Good (Blank) Not recommended



† Nuisance static. Antistatic performance may be reduced for sterile products. Barrier properties may be compromised through use.

Introduction

Understanding cleanroom classifications

Over the past few years there has been an increasing trend to change from previous classification systems used to the ISO classification systems in ISO 14644-1 (see Table 3). However, many companies have continued to use the traditional Class 100, 10,000, 100,000 room classification system from Federal Standard 209-e. In Europe, the GMPs (Good Manufacturing Practice) utilize another system - Grades A through D (see Table 4).

EU GMP guidelines are more stringent than others, requiring cleanrooms to meet particle counts at operation (during manufacturing process) and at rest (when manufacturing process is not carried out, but room air handling unit is on). Many global companies, choose to use this classification system. All of these systems are acceptable for use.

Table 3. ISO 14644-1 Air cleanliness classes for cleanrooms and clean zones (maximum particles/m³ of air).

ISO Classification Number	0.1 µm	0.2 μm	0.3 µm	0.5 µm	1.0 µm	5.0 µm	SI	English Former FED-STD-209E
ISO Class 1	10	2						
ISO Class 2	100	24	10	4				
ISO Class 3	1000	237	102	35	8		M 1.5	1
ISO Class 4	10000	2370	1020	352	83		M 2.5	10
ISO Class 5	100000	23700	10200	3520	832	29	M 3.5	100
ISO Class 6	1000000	237000	102000	35200	8320	293	M 4.5	1000
ISO Class 7				352000	83200	2930	M 5.5	10000
ISO Class 8				3520000	832000	29300	M 6.5	100000
ISO Class 9				35200000	8320000	293000		

Source: ISO 14644-1

Table 4. GMP grades - EU classification.

	Maximum particles/m³						
Class	At Rest	At Rest	In Operation	In Operation			
	0.5 µm	5 µm	0.5 µm	5 µm			
Grade A	3,520	20	3,520	20			
Grade B	3,520	29	352,000	2,900			
Grade C	352,000	2,900	3,520,000	29,000			
Grade D	3,520,000	29,000	Not defined	Not defined			

Source: EU GMPs Annex 1 - Recommended limits for particulate contamination

^{*} Tyvek® IsoClean® (Option Code CS, DS and MS) garments are most typically considered for use in GMP A-D, ISO Class 5-8. 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.

DuPont[™] **Tyvek**[®] **IsoClean**[®] range

clean-processed and sterile garments and accessories

One of the most popular products in the DuPont Controlled Environments portfolio, DuPont™ Tyvek® IsoClean® clean-processed and sterile single-use garments offer an ideal balance of protection, durability and comfort. In addition, they are specially processed to minimize particle shedding, then folded for aseptic

donning and packed in an ISO Class 4 Certified 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. Tyvek® IsoClean® garments are available in a wide variety of styles, such as coveralls, hoods or boot covers.

Gowning for GMP A&B (ISO 4/5, Class 10/100) controlled environments



DuPont[™] Tyvek[®] IsoClean[®] range

clean-processed and sterile garments and accessories



Category III



TYPE 5-B





TYPE 6-B







SAL 10⁻⁶

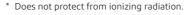
EN 1073-2* Class 2

EN 14126 ISO 11137

Unhooded coverall

model IC 183 B option DS











Benefits

- Sterility Assurance Level (SAL) of 10-6 (ISO 11137)
- Dual barrier validated packaging system (option DS) for contamination control and sterility risk management
- Packed in an ISO Class 4 Certified Cleanroom
- Internal bound seams covered with garment fabric to reinforce seam protection and reduce potential for liquid and particle penetration

Features

Unhooded coverall with bound neck. Clean-processed and gamma-sterilized. Bound seams (internal). Tyvek® covered elasticated thumb loops. Tunnelled elastication at wrists and ankles. Front zipper closure with storm flap.

Applications

Garments and accessories made of clean-processed and sterile Tyvek® IsoClean® are typically used in cleanrooms within the biotech, pharmaceutical, medical device manufacturing, food processing, cosmetics industries, as well as in other critical or controlled environments.

Reference: Model IC 183 B option DS

Colour: White: IC183 B WH DS

Size: SM to 3XL

DuPont[™] **Tyvek**[®] **IsoClean**[®] range

clean-processed and sterile garments and accessories

Product description	Category	Reference
DuPont™ Tyvek® IsoClean® Labcoat with bound neck - model IC 270 B option MS (Clean-Processed and Sterile) Labcoat available in white in sizes SM to 3XL. Bound seams. Covered elastication at wrists. Front snap closure for easy donning and doffing. Packed in a dual barrier validated packaging system (double bagged).	Cat. I	IC 270 B WH MS
DuPont™ Tyvek® IsoClean® Sleeve - model IC 501 B option MS (Clean-Processed and Sterile) Sleeve available in white and in one size. Bound seams. Tunnelled elastication at wrist and bicep. Packed in a dual barrier validated packaging system (double bagged).	Cat. III, PB [6]*	IC 501 B WH MS
DuPont™ Tyvek® IsoClean® Boot cover - model IC 458 B option MS (Clean-Processed and Sterile) Boot cover available in white, in sizes SM to XL. Bound seams. Covered elasticated leg opening. Ankle ties. Slip-retardant Gripper™ sole. 18" (45.7 cm) high. Packed in a dual barrier validated packaging system (double bagged). SM: 10" fits up to UK men's size 4.5/EU 37 MD: 12" fits up to UK men's size 6 1/2/EU 39.5 LG: 14" fits up to UK men's size 131/2/EU 48.5 XL: 16" Fits up to UK men's size 18 1/2/EU 53	Cat. III, PB [6]*	IC 458 B WH MS
DuPont™ Tyvek® IsoClean® Hood with ties - model IC 668 B option MS (Clean-Processed and Sterile) Hood available in white and in one size. Bound seams. Bound hood opening. Full face opening. Ties with loops for adjustable fit. Packed in a dual barrier validated packaging system (double bagged).	Cat. III, PB [6]*	IC 668 B WH MS
DuPont™ Tyvek® IsoClean® Hood and mask - model IC 982 B option MS (Clean-Processed and Sterile) HOOD: Bound internal seams. Bound head opening. Ties with loops for adjustable fit. MASK: Pleated polyethylene outer. 17.5 cm wide. Sterile. Blue. Items packed in a dual barrier validated packaging system (double bagged).	Cat. I	IC 982 B WH MS
DuPont™ Tyvek® IsoClean® Bouffant - model IC 729 WH option MS (Clean-Processed and Sterile) Bouffant available in white and in one size. Elastic headband. Packed in a dual barrier validated packaging system (double bagged).	Cat. I	IC 729 S WH MS
DuPont™ Sierra™ Mask - model ML 7360 - Option OS (Sterile) Mask available in white and in one size. Bound Tyvek® ties. Pleated rayon outer facing. Metal nose piece.	N/A	ML 7360 WH 0S

N/A - Not Applicable.
* Partial body protection.

DuPont[™] **Tyvek**[®] **IsoClean**[®] range

non-sterile (bulk) accessories

DuPont™ Tyvek® IsoClean® non sterile (bulk single-use accessories offer an ideal balance of protection, durability and comfort for less demanding environments.

Tyvek® IsoClean® (option codes OB, OO) garments and accessories have not been clean-processed or gamma-irradiated but manufactured in an controlled

environment. In addition, they are exceptionally low linting with high particle barrier properties. Tyvek® IsoClean® non sterile accessories are available in a wide variety of styles, such as hoods, gowns, bouffants, shoe/boot covers and sleeves.

Gowning for GMP C&D (ISO 7/8, Class 10,000/100,000) controlled environments



DuPont[™] Tyvek[®] IsoClean[®] range

non-sterile (bulk) accessories

Product description	Category	Reference
DuPont™ Tyvek® IsoClean® Labcoat with bound neck - model IC 270 B option 0B (Bulk Packed) Labcoat available in white in sizes SM to 3XL. Bound seams. Covered elastication at wrists. Front snap closure for easy donning and doffing. White.	Cat.III, PB [6]*	IC 270 B WH 0B
DuPont™ Tyvek® IsoClean® Gown - model IC 702 S option 00 (Bulk Packed) Gown available in white and in sizes SM/MD and LG/2XL. Serged seams. Bound neck with ties. Knitted cuffs. Bound ties originating at center front waist.	Cat. III, PB [6]*	IC 702 S WH 00
DuPont™ Tyvek® IsoClean® Sleeve - model IC 501 B option 00 (Bulk Packed) Sleeve available in white and in one size. Bound seams. Covered elastic at both ends. 45 cm long.	Cat. III, PB [6]*	IC 501 B WH 00
DuPont™ Tyvek® IsoClean Shoe cover - model IC 451 S WH option 00 (Bulk Packed) Shoe cover available in white and in sizes MD and LG. Fixation ties. Gripper™ sole. Stitched seams. MD: 11.75″ fits up to UK men's size 6 1/2/EU 39.5 LG: 14″ fits up to UK men's size 12 1/2/EU 47	Cat. III, PB [6]*	IC 451 S WH 00
DuPont™ Tyvek® IsoClean Boot cover - model IC 458 B WH option 00 (Bulk Packed) Boot cover available in white and in sizes MD and LG. Fixation ties. Gripper™ sole. Bound seams. MD: 12″ fits up to UK men's size 6 1/2/EU 39.5 LG: 14″ fits up to UK men's size 131/2/EU 48.5	Cat. III, PB [6]*	IC 458 B WH 00
DuPont™ Tyvek® IsoClean® Hood with ties - model IC 668 B option 00 (Bulk Packed) Hood available in white and in one size. Bound seams. Bound hood opening. Full face opening. Ties with loops for adjustable fit.	Cat. III, PB [6]*	IC 668 B WH 00
DuPont™ Tyvek® IsoClean® Bouffant - model IC 729 S option 00 (Bulk Packed) Bouffant available in white and in one size. Serged seams. Elastic headband. 54 cm diameter.	Cat. III, PB [6]*	IC 729 S WH 00
DuPont™ Sierra™ Mask - model ML 7360 option BH Mask available in white and in one size. Bound Tyvek® ties. Pleated rayon outer facing. Metal nose piece.	N/A	ML 7360 WH BH

N/A - Not Applicable.

Processing and packaging options

Processing options

Clean-processed and sterile

Clean-processed and sterile garments (option code MS, DS or CS): Garments are specially processed to minimize particle shedding, then folded to aid in aseptic donning and packed in an ISO Class 4 cleanroom. The box quantity is packed in a cardboard box with two polyethylene liners. Sterility is achieved by gamma irradiation. Radiation dosage is validated in accordance with ISO 11137 for a Sterility Assurance Level (SAL) of 10⁻⁶.

Sterile

Sterile (option code OS): Garments are folded to aid aseptic donning and individually packaged. The box quantity is packaged in a cardboard box with two

polyethylene liners. Some sterile items are folded and individually packaged 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.

Non-Sterile

Bulk (option code OB, OO or BH): Box quantities are packed in a cardboard box with two polyethylene liners. Tyvek® IsoClean® garments are individually packed, with one polyethylene liner in the cardboard box. Note: Individual packaging for sleeves, shoe and boot covers indicates that each pair has its own sealed bag. Masks may have subgroupings of individually packed items within the case.

Packaging options

Sterile packaging process for option DS

The garment is individually packed in a dual barrier validated packaging system, consisting of an inner and outer easy tear, validated, cleanroom bag. The box quantities are packed in a cardboard box with two polyethylene liners.



- 1. Outer shipping box is securely sealed. Carton displays product label, sterile dot indicator and fully traceable lot and the certificate of sterility.
- 2. Multilevel interior packaging features two polyethylene box liners. The outer liner provides protection from dust and contamination, particularly if outer box is discarded. A lot-specific Certificate of Compliance with sterile dot indicator is placed between the two liners. The inner liner is closed and allows transportation of product to a cleaner, more controlled environment.
- 3. (3a and 3b) Each garment is packed in a dual barrier packaging system, consisting of an inner and outer easy tear, validated, cleanroom bag. The validated dual barrier packaging 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.
- 4. Sterile garment consistently folded and packed to ease aseptic donning. Traceable lot numbers are stamped on each individual sterile garment.

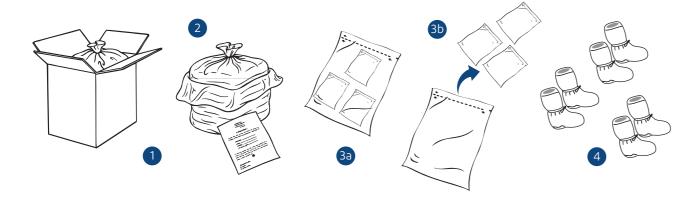
DuPont™ Tyvek® IsoClean® range Processing and packaging options

^{*} Partial body protection.

Processing and packaging options

Sterile packaging process for option MS

Items are packed in a dual barrier validated packaging system, consisting of an inner and outer easy tear, validated, cleanroom bag. The accessories are individually packed and sub-grouped together in an outer bag. The box quantities are packed in a cardboard box with two polyethylene liners. See safespec.dupont.co.uk for the exact packaging configuration details.



- Outer shipping box is securely sealed. Box displays product label, sterile dot indicator and fully traceable lot number and the certificate of sterility.
- 2. Multilevel interior packaging features two polyethylene box liners. The outer liner provides protection from dust and contamination, particularly if outer box is discarded. A lot-specific Certificate of Compliance with sterile dot indicator is placed between the two liners. The inner liner is closed and allows transportation of product to a cleaner, more controlled environment.
- 3. (3a. and 3b.) Multiple items are packed in a dual barrier packaging system, consisting of an inner and outer easy tear, validated, cleanroom bag. The validated dual barrier packaging 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.
- 4. Sterile items are consistently folded and packed to ease aseptic donning. Traceable lot numbers are stamped on each Tyvek® IsoClean® accessory.

Disclaimer

This information is based upon technical data that DuPont believes to be reliable. It is subject to revision as additional knowledge and experience becomes available. DuPont does not guarantee results and assumes no obligation or liability in connection with this information. It is the user's responsibility to determine the level of toxicity and the proper personal protective equipment needed. This information is intended for use by persons having the technical expertise to undertake evaluation under their own specific end-use conditions, at their own discretion and risk. Anyone intending to use this information should first check that the garment selected is suitable for the intended use. The end-user should discontinue use of garment if fabric becomes torn, worn or punctured, to avoid potential chemical exposure. Since conditions of use are beyond our control, we make no warranties, expressed or implied, including but not limited to warranties of merchantability or fitness for a particular purpose and assume no liability in connection with any use of this information. This information is not intended as a license to operate under or a recommendation to infringe any patent or technical information of DuPont or other persons covering any material or its use. DuPont reserves its right to make minor changes to the products featured in this catalogue.

LATEX STATEMENT: As of January 1, 2006, DuPont production specifications exclude the use of components containing natural rubber latex in the manufacture of DuPont™ Tyvek® IsoClean® and Sierra™ garments.

Anyone who begins to exhibit an allergic response during the use of DuPont products should immediately cease using these products. DuPont production specifications for Gripper™ sole exclude use of latex. Notwithstanding, DuPont cannot guarantee the absence of latex in these shoe or boot covers. Anyone who begins to exhibit allergic response during the use of DuPont products should immediately cease using these products. The incident should also be reported to DuPont.

SILICONE STATEMENT: In the past, DuPont has found that threads and zippers can be the most significant source of silicone oil contamination in garments. DuPont specifies that threads and zippers used in Tyvek® IsoClean® garments be manufactured without the use of silicone oils. Notwithstanding, DuPont cannot guarantee the absence of silicone oils on these garments. For end users with concerns about contamination with silicone oils or any other contaminants, the best practice is to audit inbound materials, including garments for those contaminants.

DuPont garments and accessories for controlled environments are not flame-resistant and should not be used around heat, flame, sparks or in potentially flammable or explosive environments. Garments made of Tyvek® should have slip-resistant or antislip materials on the outer surface of boots, shoe covers or other garment surfaces in conditions where slipping could occur.

Processing and packaging options



DuPont™ SafeSPEC™ - We're here to help





Our powerful web-based tool can assist you with finding the appropriate DuPont garment for your cleanroom environment.

safespec.dupont.co.uk

DuPont Personal Protection

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