

Pharmaceutical



Protective solutions for pharmaceutical industry applications

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Because everyone has someone depending on them to get home safely

DuPont is more focused than ever on providing innovative protection solutions and expert technical support, tailored to meet the specific needs of those working in the pharmaceutical industry around the world.

Because their safety is our business, pharmaceutical workers and operators can rely on the world-class people, products and innovation that have made DuPont a trusted partner in personal protection.

With a wide range of industry-leading personal protective equipment (PPE) solutions and a global network of PPE specialists, technical experts and manufacturing, DuPont is uniquely suited to provide the protection and comfort every worker deserves to help them face a range of workplace hazards with confidence, as well as contamination control for every product in diverse pharmaceutical environments.





Our brands

Tyvek® IsoClean®

Tyvek® IsoClean® offers a range of durable, comfortable and lightweight single-use garments, developed especially for cleanrooms and controlled environments, that feature an inherent barrier to dry particles, microorganisms and liquids, as well as contamination control.

Tyvek®

Tyvek® coveralls provide a protective barrier built into the material for increased protection to repel low concentrated inorganic liquids and aerosols while preventing solid particles from adhering.

Tychem®

Tychem® garments deliver durable protection and help offer strong permeation barrier against a wide range of chemicals.

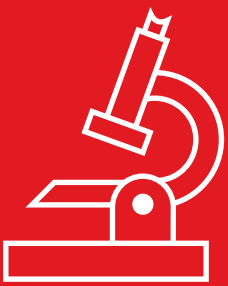
Nomex®

Nomex® offers a tested and proven portfolio of protective solutions that continues to meet or exceed global standards for heat, flame and arc flash protection.

Kevlar®

Gloves made with Kevlar® deliver industry-leading cut protection and built-in heat and flame resistance, while providing the dexterity and comfort workers want.

Are your workers, processes and environments really protected?

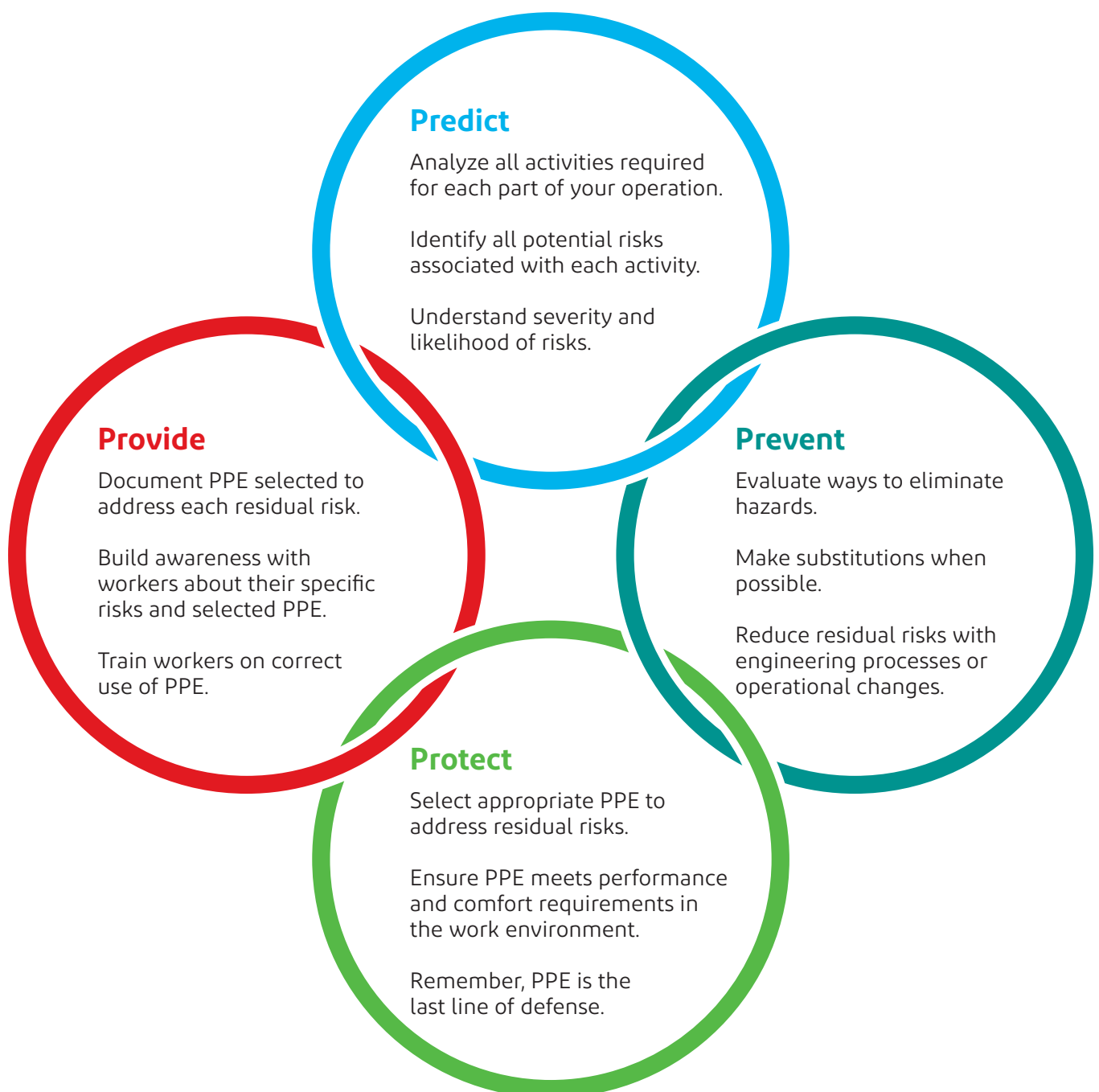


Diverse pharmaceutical manufacturing applications require protection from chemical, biological, mechanical and heat & flame hazards. What's more, processes performed in cleanrooms and controlled environments require protection of finished products and processes from potential contamination sources.

Providing workers with the protection they need for the hazards they face, as well as ensuring the best quality of manufactured products is a major responsibility. DuPont Personal Protection has the in-depth knowledge, unparalleled expertise and broad portfolio of PPE solutions to help keep you, your products and your working environment safe.

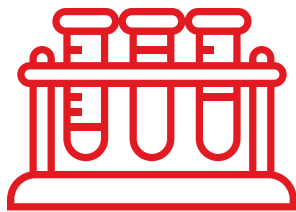
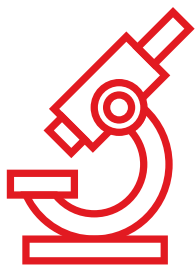
DuPont PPE solutions are designed to meet or exceed global standards for protection and performance, while meeting the Good Manufacturing Practice (GMP) requirements for the different cleanroom classes. Therefore, DuPont PPE solutions can be part of a holistic contamination control strategy.

To help you in the decision-making process, from risk assessment through implementation, we recommend using the 4P methodology:

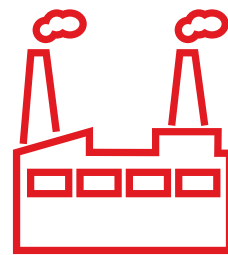


Multiple workplace hazards in a dynamic work environment

The pharmaceutical industry consists of very complex manufacturing processes that include handling chemical and biological substances, working in cleanrooms and controlled environments, as well as working in explosive zones and with heavy machinery.



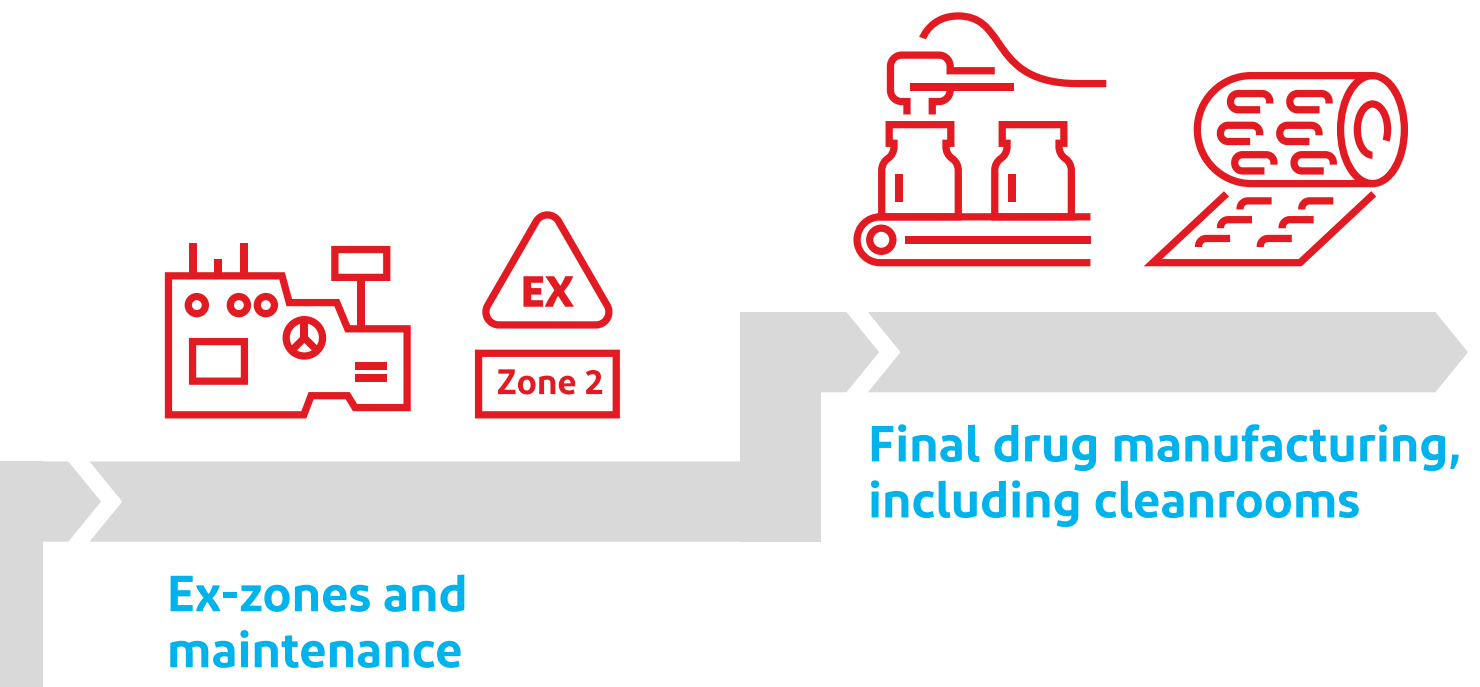
Research and development



APIs manufacturing and intermediates manufacturing

As a result, the selection of PPE varies broadly depending on the type of application. DuPont products can be used in every step of the manufacturing process, from research and development laboratories through active pharmaceutical ingredients (APIs) manufacturing to final drug development.

Refer to the graphic below to see where DuPont PPE solutions can be used in the pharmaceutical industry.





Protection
for every
application



R&D

Research laboratories

Tasks

Synthesis processes

Extraction processes

Fermentation processes

Hazards

Exposure to solvents and small quantities of potentially harmful chemicals

Contamination of manufacturing process by personnel

Available PPE options

Research laboratories require protection for the workers performing tasks related to chemical synthesis, extraction and fermentation processes where chemical residues can contact skin. The sensitive processes in these labs also need protection against contamination by people, which can be achieved when workers wear clean (or clean and sterile) protective clothing.



Tychem® 2000 C and Tychem® 6000 F sleeves

These sleeves are 50-cm long and feature wide elastics at cuffs and upper arm. Specially designed for use with Tychem® apparel, Tychem® accessories can help offer enhanced protection for body parts that are more exposed to hazardous substances such as solvents. A shin-length gown made of Tychem® 2000 C and Tychem® 6000 F fabric is also available. Detailed permeation data is available on our website.



Cat III



Type PB [3-B]

EN 14126



Tychem® 6000 F gown

Shin-length gown with wrap-over rear closure, hook-and-loop neck closure and waist ties. Elasticated wrists. Specially designed for use with Tychem® apparel, Tychem® accessories can help offer enhanced protection for body parts that are more exposed to hazardous substances. Sleeves made of Tychem® 6000 F are also available. Detailed permeation data is available on our website.



Cat III



Type PB [3-B]

EN 14126



Tyvek® 500 labcoat

Labcoat with press studs, model PL30NP. Stitched internal seams. Collar. Press stud closures. No pockets. Elasticated cuffs (not tunnelled). Suitable for GMP C&D cleanrooms. There are also three other labcoat designs available.



Cat III



Type PB [6-B]

EN 14126



Tyvek® IsoClean® labcoat 270 B MS

Labcoat suitable for operations performed in cleanrooms and controlled environments (GMP A&B). Labcoat with bound neck and bound internal seams. Clean-processed and gamma-sterilized. Tunnelled elastication at wrists. Front snap closure for easy donning and doffing. Aseptically folded. Also available as non-sterile (bulk) option (suitable for GMP C&D cleanrooms).



Cat III



Type PB [6-B]

EN 14126



ISO 11137-1



Helmke Drum



Tyvek® IsoClean® sleeve 501 B MS

Sleeve suitable for operations performed in cleanrooms and controlled environments (GMP A&B). Clean-processed and gamma-sterilized sleeve with bound internal seams. Tunnelled elastication at wrist and biceps. Also available as non-sterile (bulk) option (suitable for GMP C&D cleanrooms).



Cat III



Type PB [6-B]

EN 14126



ISO 11137-1



Helmke Drum

For a full list of PPE solutions, visit [SafeSPEC™](#).





R&D

Pharmaceutical and toxicological laboratories

Tasks

Working with animals

Microbiological tasks

Physical and chemical analyses

Quality control

Sample taking

Hazards

Exposure to corrosive liquids, solid particulates, airborne dusts and animal scratches

Contamination of manufacturing process by personnel

Available PPE options

During the R&D phase, pharmaceutical and toxicological laboratories involve a variety of tasks requiring protection of the workers from chemicals and biological substances, as well as mechanical injuries (e.g., animal scratches). The sensitive processes in these labs also need protection against contamination by people, which can be achieved when workers wear clean (or clean and sterile) protective clothing.



Tyvek® 600 Plus

Coverall with hood, serged and over-taped seams, and a self-adhesive Tyvek® storm flap and chin strap. Also available with socks. Suitable for GMP C&D cleanrooms.



Cat III

EN 1149-5



Type 4-B

EN 1073-2



Type 5-B



Type 6-B

EN 14126



Tyvek® 500 Xpert

Hooded coverall with stitched external seams and an optimized design for very low inward leakage. Garment available in different colors—white, blue and green—to allow color coding for different areas. Suitable for GMP C&D cleanrooms.



Cat III

EN 1073-2



Type 5-B



Type 6-B



EN 14126



EN 1149-5



Tyvek® 500 Labo

Lightweight, comfortable and durable coverall with attached, slip-retardant overshoes. Suitable for GMP C&D cleanrooms.



Cat III

EN 1073-2



Type 5-B



Type 6-B



EN 14126



EN 1149-5



Tychem® 2000 C sleeve

This sleeve is 50-cm long and features wide elastics at cuffs and upper arm. Specially designed for use with Tychem® apparel, Tychem® accessories can help offer enhanced protection for body parts that are more exposed to hazardous substances. A gown made of Tychem® 2000 C is also available. Detailed permeation data is available on our website.



Cat III



Type PB [3-B]

EN 14126



Tyvek® 500 labcoat

Labcoat with press studs, model PL30NP. Stitched internal seams. Collar. Press stud closures. No pockets. Elasticated cuffs (not tunnelled). Suitable for GMP C&D cleanrooms.



Cat III



Type PB [6-B]

EN 14126



For a full list of PPE solutions, visit [SafeSPEC™](#).



DuPont - SafeSPEC™



API manufacturing

Chemical processes

Tasks

Pharmaceutical reactor cleaning

Dry freezing APIs

Quality control sample taking

Hazards

Exposure to APIs

Available PPE options

API manufacturing, where chemical processes are used, requires chemical protective clothing (Cat III Type 3, 4, 5 and 6) that provide protection against fine particles and permeability to both air and water vapor, as well as the ability to repel water-based liquids and aerosols. Some processes also need protection against highly concentrated organic and inorganic chemicals.



Tychem® 6000 F FaceSeal

Hooded coverall with rubber seal on hood for tight fit around respirator. Elasticated waist for an optimal fit, attached undergloves, dissipative socks with boot flap and back entry for enhanced wearer protection. This coverall offers excellent chemical permeation resistance to an extensive range of chemicals, including organic chemicals, particulates and biohazards.



Cat III

EN 14126



Type 3-B

EN 1149-5



Type 4-B

EN 1073-2



Type 5-B



Type 6-B



Tychem® 6000 F Plus

Hooded coverall with elasticated face, wrists, waist and ankles for an optimal fit. Features double cuffs, knitted inner cuffs and thumb loops to prevent sleeves from riding up. Front entry with double zipper, double flap and adhesive tape at outer flap.



Cat III

EN 14126



Type 3-B

EN 1149-5



Type 4-B

EN 1073-2



Type 5-B



Type 6-B



Tyvek® 600 Plus

Coverall with hood, serged and over-taped seams, and a self-adhesive Tyvek® storm flap and chin strap. Also available with socks. Suitable for GMP C&D cleanrooms.



Cat III

EN 1149-5



Type 4-B

EN 1073-2



Type 5-B



Type 6-B

EN 14126



Tyvek® 500 Xpert

Hooded coverall with stitched external seams and an optimized design for very low inward leakage. Garment available in different colors—white, blue and green—to allow color coding for different areas. Suitable for GMP C&D cleanrooms.



Cat III

EN 1073-2



Type 5-B



Type 6-B

EN 14126



EN 1149-5



For a full list of PPE solutions, visit [SafeSPEC™](#).



DuPont - SafeSPEC™



API manufacturing

Biological processes

Tasks

Offloading organic chemicals
from trucks

Working with solvents

Cleaning tanks/vessels

Hazards

Exposure to APIs

Available PPE options

API manufacturing with biological processes requires chemical protective clothing and gloves (Cat III Type 3, 4, 5 and 6) that offer excellent chemical permeation resistance to an extensive range of chemicals.



Tychem® 6000 F FaceSeal

Hooded coverall with rubber seal on hood for tight fit around respirator. Elasticated waist for an optimal fit, attached undergloves, dissipative socks with boot flap and back entry for enhanced wearer protection. This coverall offers excellent chemical permeation resistance to an extensive range of chemicals, including organic chemicals, particulates and biohazards.



Cat III

EN 14126



Type 3-B

EN 1149-5



Type 4-B

EN 1073-2



Type 5-B



Type 6-B



Tychem® 6000 F gown

Shin-length gown with wrap-over rear closure, hook-and-loop neck closure and waist ties. Double cuffs for increased protection and tighter connection with gloves. Mandarin collar for improved neck and throat area closure. Elasticated wrists. Detailed permeation data is available on our website. Suitable for GMP C&D cleanrooms.



Cat III



Type PB [3-B]

EN 14126



Tychem® 2000 C gown

Shin-length gown with wrap-over rear closure, hook-and-loop neck closure and waist ties. Double cuffs for increased protection and tighter connection with gloves. Mandarin collar for improved neck and throat area closure. Elasticated wrists. Detailed permeation data is available on our website. Suitable for GMP C&D cleanrooms.



Cat III



Type PB [3-B]

EN 14126



For a full list of PPE solutions,
visit [SafeSPEC™](#).



DuPont - SafeSPEC™



Final drug manufacturing

Aseptic processes

Tasks

Aseptic manufacturing of vaccines, prefilled syringes and eye drops

Hazards

Microbiological and particulate contamination of the product

Usual working environment type

GMP A&B Cleanrooms

Available PPE options

During aseptic manufacturing, protection of the process and the final product is crucial. This can be achieved by using strict operating procedures, appropriate equipment and PPE that minimizes contamination risks. At the same time, it is important to provide the workers with durable, comfortable PPE that will protect them from exposure to chemical or biological hazards.



Tyvek® IsoClean® unhooded coverall IC 183 B DS

Clean-processed and gamma-sterilized garment with bound internal seams and tunnelled elastics at the wrists and ankles.



Cat III



Type 5-B



Type 6-B

EN 14126



EN 1073-2



ISO 11137-1



Helmke Drum



Tyvek® IsoClean® boot cover IC 458 B MS

Clean-processed and gamma-sterilized boot cover with a Gripper™ sole for reduced slip. Also available as non-sterile (bulk) option.



Cat III



Type PB [6-B]

EN 14126



ISO 11137-1



Helmke Drum



Tyvek® IsoClean® hood IC 668 B MS

Clean-processed and gamma-sterilized hood with bound internal seams and a full-face opening. Also available as non-sterile (bulk) option.



Cat III



Type PB [6-B]

EN 14126



ISO 11137-1



Helmke Drum



Tyvek® IsoClean® sleeve IC 501 B MS

Clean-processed and gamma-sterilized sleeve with bound internal seams. Tunnelled elastics at wrists and biceps. Also available as non-sterile (bulk) option.



Cat III



Type PB [6-B]

EN 14126



ISO 11137-1



Helmke Drum

Important:

Packaging and sterility

Clean-processed and sterile garments and accessories (option codes MS and DS) 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.

Bacterial and particle filtration efficiency

Tyvek® IsoClean® CS fabric has a bacterial filtration efficiency of 98.4% and a particle filtration efficiency of 67% (5X more restrictive to fine particulates than reusable polyester fabrics) and is therefore very well suited for protecting both the cleanroom and the operators.

For a full list of PPE solutions, visit SafeSPEC™.



DuPont - SafeSPEC™



Final drug manufacturing

Non-aseptic processes

Tasks

Wet granulation, compounding and coating operations

Dispensing, drying, milling and blending operations

Hazards

Exposure to corrosive liquids, solid particulates and airborne dusts

Usual working environment type

GMP C&D Cleanrooms

Available PPE options

Manufacturing of dosage forms, such as pills, liquids, powders or pastes, requires foremost the protection of the worker performing a variety of tasks related to the preparation of the pharmaceutical product. Protective garments of Cat III Type 4, 5 or 6 offering protection against small particles, combined with durability and comfort for the wearer, are essential. Protecting the process and product from contamination should also be taken into consideration.



Tyvek® 600 Plus

Coverall with hood, serged and over-taped seams, and a self-adhesive Tyvek® storm flap and chin strap. Also available with socks.



Cat III

EN 1149-5



Type 4-B

EN 1073-2



Type 5-B



Type 6-B

EN 14126



Tyvek® 500 Xpert

Hooded coverall with stitched external seams and an optimized design for very low inward leakage. Garment available in different colors—white, blue and green—to allow color coding for different areas.



Cat III

EN 1073-2



Type 5-B



Type 6-B



EN 14126



EN 1149-5



Tyvek® 500 Labo

Lightweight, comfortable and durable coverall with attached, slip-retardant overshoes.



Cat III

EN 1073-2



Type 5-B



Type 6-B



EN 14126



EN 1149-5



Tyvek® IsoClean® boot cover IC 458 B 00

Non-sterile, bulk packed boot cover with a Gripper™ sole for reduced slip.



Cat III



Type PB [6-B]

EN 14126



Tyvek® IsoClean® sleeve IC 501 B 00

Non-sterile, bulk packed sleeve with bound internal seams. Tunnelled elastication at wrists and biceps.



Cat III



Type PB [6-B]

EN 14126



For a full list of PPE solutions, visit [SafeSPEC™](#).





Working in explosive zones

Tasks

Daily production tasks

Activities during solvent extraction

Hazards

Exposure to electric arc

Exposure to flash fire

Exposure to pressurized steam and extreme heat

Available PPE options

Ex-zones represent high risk of potential burn injuries. For this reason, it is important to protect the workers against heat, flame and electric arc hazards.



Nomex® Essential Arc

Nomex® Essential Arc is engineered to provide arc flash protection for workers performing electrical tasks. Along with its mechanical properties, it has enhanced durability, which means fewer garment replacements.

EN ISO 11612



A1 B1 C1 F1

IEC 61482-1-1



ATPV >8 cal/cm²

EN 1149-5



Nomex® Comfort

The unique fabric technology of Nomex® Comfort offers the proven protection of Nomex® in a lightweight, breathable, quick-drying fabric. It offers better protection at longer exposures and higher temperatures. Nomex® is resistant to many chemicals and oil stains are washed out easier than with standard cotton garments.

EN ISO 11612



A1 B1 C1 F1

IEC 61482-1-1



ATPV >8 cal/cm²

EN 1149-5



Nomex® Xtreme Arc

Nomex® Xtreme Arc provides an arc thermal performance value (ATPV) of 12 to 19 cal/cm², making it the ideal choice for workers confronted with high-risk electrical exposure. Nomex® Xtreme Arc delivers high-performance, single-layer, comfortable electric arc protection.

EN ISO 11612



A1 B1 C1 F1

IEC 61482-1-1



ATPV >12 cal/cm²

EN 1149-5



SHOWA 240

This 13-gauge glove with Kevlar® liner offers flame resistance and protection against electric arc. The sponge neoprene palm coating provides good grip when secure grip is required. The Kevlar® liner gives medium cut-resistant protection performance.

EN 388:2016



3X31C

EN 407:2011



42212X

For a full list of PPE solutions, visit [SafeSPEC™](#).



DuPont - SafeSPEC™



Machinery maintenance

Tasks

Handling sharp objects

Manual handling of materials, machinery and equipment

Hazards

Manual contact with sharp edges

Exposure to electric arc

Available PPE options

Maintenance activities require effective hand protection against cut hazards. In some cases, electric arc also represents a threat.



SHOWA 240

Lightweight and comfortable, this 13-gauge glove is lined with Kevlar® and has a sponge neoprene palm coating. Flame-resistant Kevlar® enables protection against arc flash up to level 2. Flat dipped sponge neoprene coating provides enhanced grip and the anatomical design helps prevent hand fatigue.

EN 388:2016



3X31C

EN 407:2011



42212X



Nomex® Essential Arc

Nomex® Essential Arc is engineered to provide arc flash protection for workers performing electrical tasks. Along with its mechanical properties, it has enhanced durability, which means fewer garment replacements.

EN ISO 11612



A1 B1 C1 F1

IEC 61482-1-1



ATPV >8 cal/cm²

EN 1149-5



ATG Maxiflex Cut 34-1743

This 18-gauge glove made with Kevlar® offers superb dexterity and comfort combined with high levels of cut resistance (cut level D). Kevlar® material also provides protection when handling hot objects up to 100°C. The foam nitrile palm coating provides excellent grip.

EN 388:2016



4331D

EN 407:2004



SHOWA S-TEX 581

Kevlar® liner provides high levels of cut resistance up to level E (EN 388:2016), while also offering protection when handling hot objects. Comfortable 13-gauge liner offers excellent dexterity and the foam nitrile palm coating allows for secure handling.

EN 388:2016



4331D

For a full list of PPE solutions, visit [SafeSPEC™](#).

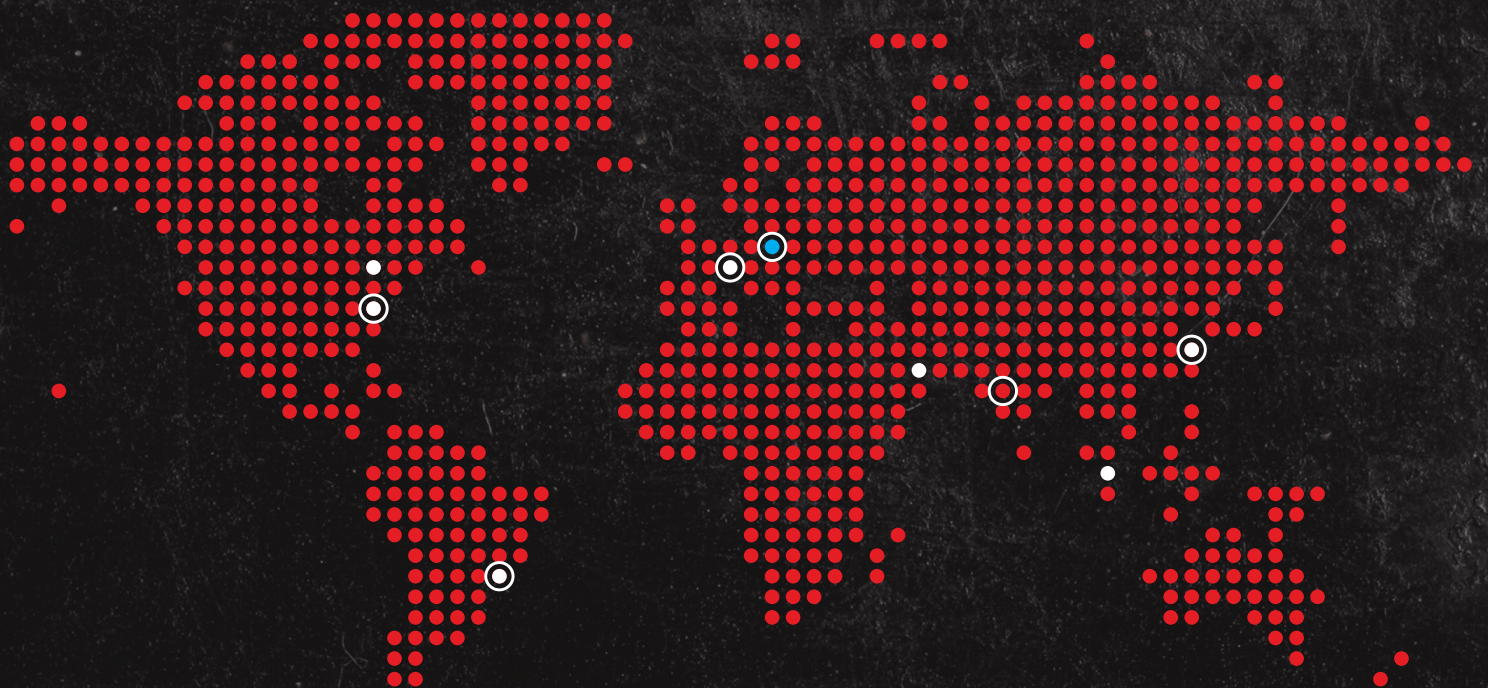


DuPont - SafeSPEC

Global reach

With operations in 96 countries and technical centers staffed with experts across the globe, we are here to provide you with the support you need when choosing the right PPE.

Our Thermo-Man® (life-sized thermal burn injury evaluation) and Arc-Man® (arc flash injury evaluation) units provide compelling demonstrations that help educate safety managers about the durability and heat, flame and electric arc resistance that DuPont Safety PPE delivers.

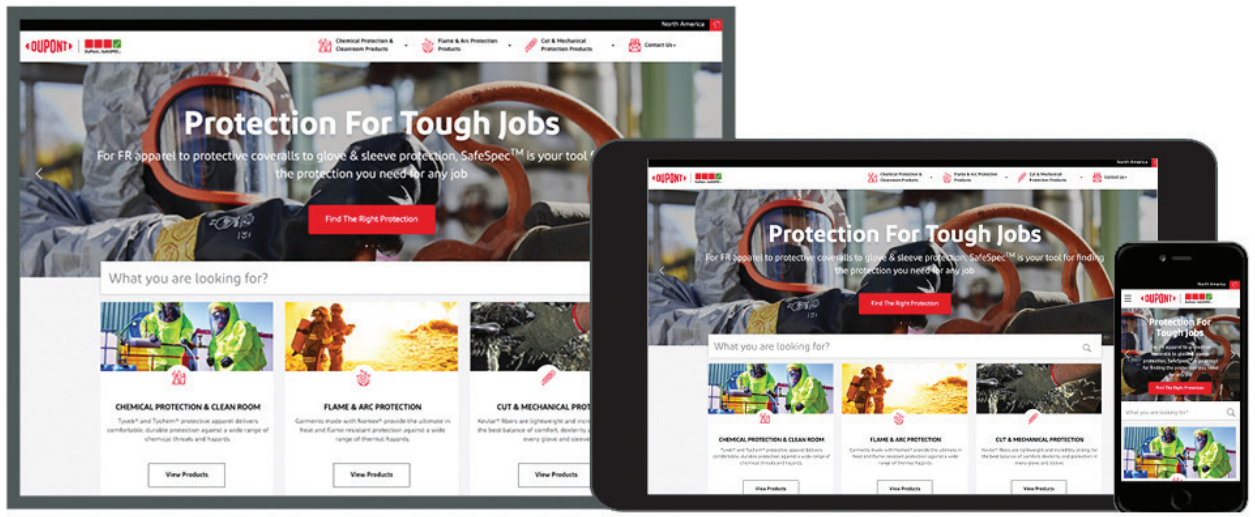


We're here to help

DuPont™ SafeSPEC™, our powerful web-based tool, can assist you with finding appropriate DuPont garments for chemical, controlled environment, thermal, electric arc and mechanical hazards.

SafeSPEC™ has a full permeation test database and allows you to search by either hazard or industry to help you find the right protection for the job at hand.

safespec.dupont.co.uk



DUPONT™



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«DUPONT»

Kevlar | **Nomex** | **Tyvek** | **Tychem**

DuPont Personal Protection

safespec.dupont.co.uk

dpp.dupont.com

 **DuPont Personal Protection**

 **@DuPontPPE**

WARNING: Tyvek®, ProShield®, and most Tychem® garments, including Tychem® 2000 Tape, should not be used around heat, flames, sparks or in potentially flammable or explosive environments.

Do not wear non-flame-resistant garments in potentially flammable or explosive environments. Instead, consider use of flame-resistant or secondary flame-resistant garments, which must be worn over primary flame-resistant garments.

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