



— Comprehensive Guide to Protecting Against Hazards in the Handling of Oncology Drugs

Advancements in medicine, patient care, and treatments renew hope for cancer patients each year. While cytostatic drugs are crucial in effectively destroying cancer cells, they also carry potential risks for those handling them.

Therefore, it is essential for personnel working with these compounds, many of which are potent carcinogens, mutagens, or reproductive toxins, to have adequate protection.

DuPont Personal Protective Solutions - **Tyvek® IsoClean®**, **Tyvek®**, and **Tychem®** not only offer confidence to people involved in cancer treatments but also protect the cytostatics from contamination and meet or exceed the highest drug manufacturing standards such as the GMP standards.

► People in contact with cytostatic substances are involved in:

- » Pharmaceutical drug manufacturing
- » Drug preparation in hospitals and oncological centers
- » Handling ready-to-administer chemotherapy drugs to patients
- » Handling patient waste and waste disposal
- » Handling cytostatic spills and accidents
- » Drug transportation and storage

► Understanding the Dangers: Why Protection Matters

Employee protection

Prioritizing all safety measures is crucial for ensuring employee safety when handling cytostatics, similar to hazardous substance management. It's essential to exercise caution to prevent the generation of cytostatic aerosols and dust and to avoid contamination during the production, preparation, provision, disposal, storage, and transportation of these substances. Given that even minimal contact with cytostatic substances can pose severe health risks, using appropriate personal protective equipment (PPE) is indispensable to ensure adequate protection in any situation where contact is possible.

► Hazards faced by the staff when handling Cytostatic Drugs

Dust: Defective injection vials containing dry solids may lead to the generation of harmful airborne particles during preparation.

Liquids: Transfer and dispensing of dissolved substances can result in potential exposure to liquid cytostatics.

Aerosol Formation: Dissolving dry solids may lead to the formation of cytostatic aerosols, posing an inhalation risk.

Accidental Drops: Inadvertent dropping off containers containing cytostatics may lead to spills and exposure.



▶ Product Protection

Conducting a hazard assessment and comprehending the specific application's requirements are crucial in identifying the most efficient personal protective measures. In addition to safeguarding individuals, it is imperative to shield products from potential contamination by human sources, such as skin particles, hair, lint, or clothing-related particles. Ensuring product integrity and adhering to relevant aseptic procedures and GMP guidelines are as crucial as utilizing personal protective equipment.

▶ Minimizing Risks Through Personal Protective Clothing

In the spirit of prevention being the best form of protection, every person handling cytostatic substances, whether pharmaceutical operators or nurses in most countries globally, is mandated by law to be equipped with the requisite technical and organizational measures and use CE-compliant personal protective equipment (PPE).

Quality Standards for Oncology Protective Apparel and Cleanroom Clothing:



Material:

- Low-linting & low particle shedding.
- Effective in particle retention & liquid repellency.



Design:

- Long sleeves, closed front.
- Tight cuffs and burst-proof seams.
- Sufficiently tight to minimize particle accumulation.



Comfort:

- Breathable, comfortable, and well-fitting.



Additional Requirements for Handling Cytostatics:

- Good electrostatic discharge efficiency.
- Ability to be sterilized.

▶ Effective Protection for Employees and Products

Various hazards, such as dust generated during preparation, liquids during transfer and dispensing, aerosol formation, and the accidental dropping of containers, necessitate effective protection measures.

The National Institute for Occupational Safety and Health (NIOSH) provides essential guidelines for PPE use when working with hazardous drugs:

- » Wear gowns when there's a risk of splash or spill.
- » Change gowns every two to three hours or immediately after a spill or splash if the gowns in use offer no permeation data.
- » Avoid wearing gowns outside the compounding or administration area to prevent drug contamination from spreading.
- » Dispose of gowns after each use, as reusing them increases the likelihood of chemical exposure.

DuPont's **comprehensive**, one-stop PPE solutions result from our commitment to offering superior protection to workers globally.

- » Deep market insight, technical expertise, and application know-how
- » Global reach and local support

Robust "one-stop" solution portfolio and innovation pipeline

▶ Understanding Protective Clothing Fabrics

When considering protective clothing for use with cytostatics, it is crucial to know different fabric technologies as they often exhibit widely varying performance attributes. Below are brief overviews of single-use **Tyvek®** fabric, reusable textiles, and essential considerations for handling cytostatics.

Single-Use Tyvek® Material:

Material Structure: Unique and versatile, Tyvek® offers a high level of barrier protection, abrasion resistance, and comfort.

Low-Linting: Tyvek® garments have a smooth surface, minimizing particle adhesion. **Tyvek® IsoClean®** offers the lowest linting in the entire DuPont portfolio.

Bacterial Filtration Efficiency: Tyvek® IsoClean® coveralls can filter out bacteria, with CE certification as Category III PPE.

Reusable Textiles:

Woven Structure: Typically, reusable textiles or polyester garments have a woven structure with pores.

Barrier Properties: They are subject to multiple cycles of wearing, laundering, and sterilization, which can negatively impact barrier properties and durability.

High risk of re-contamination: With the garments being re-used often, the risk of contamination increases with every use.

Certification: Reusable polyester cleanroom clothing is typically not certified as personal protective equipment.

▶ DuPont's Comprehensive Cytostatic Contamination Protective Solutions

The protective apparel ranges **Tyvek® IsoClean®**, **Tyvek®**, and **Tychem®** play a crucial role in instilling confidence among those involved in cancer treatments.



Tyvek® IsoClean®: Exemplifying Cleanroom Excellence and Microbiological Protection

Cat. III Tyvek® IsoClean® coveralls, designed for cleanrooms and controlled environments with high microbiological protection requirements, are available in clean-processed and sterile options. They provide full-body protection and are specifically crafted for cleanroom applications, suitable for environments with the highest need for microbial protection. CE-certified and ideal for cleanrooms up to GMP A&B, ISO 4/5, and CLASS 10/100, these suits and other products in the range, like hoods, sleeves, and shoe or boot covers, enable complete body protection from head to toe. With a bacterial filtration efficiency of > 98%, Tyvek® IsoClean® coveralls can filter out bacteria.

Tyvek®: Barrier Protection for Cytostatic Production

Tyvek® garments are low-linting and have a smooth surface, providing very little foothold for particle adhesion. Depending on the need, some models offer protection against liquid chemicals or liquid chemicals under pressure (Type 3 and Type 4). In addition, protective garments produced from Tyvek® can be easily sterilized using conventional methods.

Tyvek® 800 J - type 3/4/5/6 coveralls offer the following safety and comfort benefits:



- Fabric and seams offer a chemical permeation barrier to low-concentration water-based inorganic chemicals
- Serged and over-taped seams for protection and strength
- Self-adhesive chin flap for the tight seal of the suit to the mask
- Elastic face, wrists, and ankles, as well as glued-in elastic waist
- Elastic thumb loops keep sleeves in place

Tyvek® 600 Plus - type 4/5/6 coveralls offer the following safety and comfort benefits:



- Fabric and seams offer a chemical permeation barrier to low-concentration water-based inorganic chemicals
- Serged and over-taped seams for protection and strength
- Self-adhesive chin flap for the tight seal of the suit to the mask
- Elastic face, wrists, and ankles, as well as glued-in elastic waist
- Elastic thumb loops keep sleeves in place

Tychem®: Comprehensive Protection against Inorganic and Organic Chemical Hazards

Tychem® 2000:

Tychem® 2000 combines a **Tyvek®** substrate with a polymer barrier coating, ensuring 100% particle-tight protection against a broad spectrum of inorganic chemicals and biological hazards.

It provides robust protection against a wide range of inorganic chemicals, offering a reliable defense for various applications with high exposure levels.

Accessories made of **Tychem® 2000** provide additional protection from inorganic chemicals for body parts subjected to high levels of exposure.

▶ Permeation to Cytostatic Agents

Appropriate technical documentation, such as cytostatic permeation data, must accompany PPE to prove its performance properties. Garment specifiers or users must clearly understand the technical properties of the various materials for a given application.

Permeation is the process where liquid, vapor, or gas chemicals move through protective clothing material at a molecular level. Measuring permeation in PPE fabrics is essential for choosing the right protective fabric, garment, or accessory for specific applications during risk assessment.

Understanding the toxicity and consequences of short- or long-term exposure to hazards is crucial, and consulting chemical permeation data is vital to ensuring adequate protection against specific chemicals.

▶ Choosing the Right Protective Clothing: A Nine-Step Approach

Selecting appropriate protective clothing involves a systematic nine-step process, considering hazards at every stage.

- 01 Identify the hazard
- 02 Determine minimum protection levels needed
- 03 Assess hazard toxicity
- 04 Determine fabric performance requirements
- 05 Determine mechanical performance requirements
- 06 Comfort considerations
- 07 Choose the right supplier
- 08 Identify correct product usage
- 09 Perform a wear test



DuPont offers a comprehensive approach to workplace safety with its global team of experts and the **DuPont™ SafeSPEC™** web tool, featuring an extensive database of permeation test results. This tool aids in selecting the right PPE solutions tailored to the specific hazards workers face at each site.

For a personalized experience, request a wear-trial form through your DuPont representative or distributor. This will guide you to a garment choice that meets all essential criteria: fit, function, comfort, performance, durability, and safety.

In the pharma industry, DuPont's innovative protection solutions and expert technical support are designed to address the unique needs of workers worldwide. Contact us to discover how we can enhance the safety of your workforce. #DuPontPPE #Tyvek #Tychem #Safety #PPE

Note - Users are encouraged to consult DuPont for comprehensive permeation data or to check the permeation data for each cytostatic drug in DuPont SafeSPEC™.

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The permeation data published have been generated for DuPont by independent accredited testing laboratories according to the test method applicable at that time (EN369, ASTM F739, EN 374-3, EN ISO 6529 (method A and B) or ASTM D6978). The data is typically the average of three fabric samples tested. Cytostatic drugs testing have been performed at a test temperature of 27°C according to ASTM 6978 or according to EN ISO 6529 with the additional reporting of a normalized breakthrough time at 0.01 µg/cm²/min. A different temperature may have significant influence on the breakthrough time. Permeation typically increases with temperature. Permeation data are usually measured for single chemicals. The permeation characteristics of mixtures can often deviate considerably from the behaviour of the individual chemicals.

Permeation data for Tyvek® is applicable to white Tyvek® only and is not applicable for other Tyvek® styles or colours. Breakthrough time is not the same as safe wear time.

Breakthrough time alone is insufficient to determine how long a garment may be worn once the garment has been contaminated. Safe user wear time may be longer or shorter than the breakthrough time depending on the permeation behaviour of the substance, the toxicity of the substance and the exposure conditions. Breakthrough times are indicative of the barrier performance, but results can vary between the test methods and laboratories.

Please use the permeation data as part of the risk assessment to assist the selection of a protective fabric, garment or accessory suitable for your application. Working conditions, exposure conditions (e.g. temperature, pressure, concentration, physical state), and the toxicity data for the chemical need to be taken into account. The information provided herein corresponds to our knowledge on the subject at the date of its publication. This information may be subject to revision as new knowledge and experience becomes available. The data provided fall within the normal range of product properties and relate only to the specific material designated; these data may not be valid for such material used in combination with any other materials or additives or in any process, unless expressly indicated otherwise. The data provided should not be used to establish specification limits or used alone as the basis of design; they are not intended to substitute for any testing you may need to conduct to determine for yourself the suitability of a specific material for your particular purposes. Since DuPont cannot anticipate all variations in actual end-use conditions DuPont makes no warranties and assumes no liability in connection with any use of this information. Nothing in this publication is to be considered as a license to operate under or a recommendation to infringe any patent rights.



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