

Protective clothing for biohazards



What is a biohazard?

Biohazards, or biological hazards, can adversely affect human health in a variety of ways and can be pathogenic, sensitizing or toxic. Biohazards include microorganisms, such as bacteria, viruses and fungi; and biological materials, such as blood, feces and urine. The severity of biohazards can range from relatively mild illnesses and allergic reactions to serious medical conditions including death.

Biosafety and biosecurity

Biosafety and biosecurity are related, but not identical, concepts. A risk assessment must be carried out to determine the risk to worker health and safety by looking at the type of infective agent; the nature of the activity; the type and extent of contact with the biological agent; and effective exposure controls and disinfection methods. Biosafety programs reduce or eliminate exposure of individuals and the environment

to potentially hazardous biological agents. Biosafety is achieved by implementing various degrees of facility control and containment, through facility design and access restrictions, personnel expertise and training, use of containment equipment, and safe methods of managing infectious materials. The objective of biosecurity is to prevent loss, theft or misuse of microorganisms, biological materials and research-related information. This is accomplished by limiting access to facilities, research materials and information.

Biohazard classifications*

There are two main biohazard classifications. Risk Groups classify microorganisms and Biosafety Levels classify biohazard controls. The four Biosafety Levels align with the respective Risk Groups. Controls and containment for each Biosafety Level include facility design, equipment, work practices and personal protective equipment (PPE) suitable for the relevant Risk Group.

Biosafety Level 4 (BSL-4)

- Includes Risk Group 4 (RG-4) hazards, agents associated with serious or lethal disease for which preventative and therapeutic interventions are not typically available
- High containment needed for organisms such as Ebola virus and Marburg virus

Biosafety Level 3 (BSL-3)

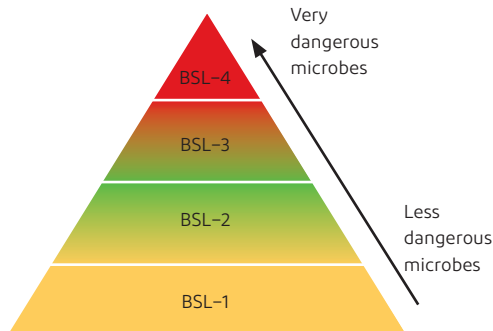
- Includes Risk Group 3 (RG-3) hazards, agents associated with serious or lethal diseases for which preventative or therapeutic interventions may be available
- Substantial containment needed for organisms such as *M tuberculosis* and *B anthracis*

Biosafety Level 2 (BSL-2)

- Includes Risk Group 2 (RG-2) hazards, agents associated with diseases which are less serious or for which preventative or therapeutic interventions are available
- Moderate containment needed for organisms such as bloodborne pathogens and *Legionella*

Biosafety Level 1 (BSL-1)

- Includes Risk Group 1 (RG-1) hazards, agents that don't normally cause disease in healthy adult humans or animals
- Minimal containment needed for organisms such as *B subtilis* and most *E coli*



Test methods for PPE

There is no single test that qualifies a garment for bloodborne pathogens (BBP) or other biohazard protection. Manufacturers of PPE make many claims regarding BBP protection. Often these claims focus on “passing” a specific ASTM test. However, BBP applications can be very different, and the PPE needed varies from situation to situation. To select an appropriate garment, employers must understand their workplace hazard and how a given test method may be used to meet their obligations under the BBP regulations. This document provides information to help end users understand manufacturers’ claims about garment BBP performance.

OSHA Bloodborne Pathogens Regulation (29 CFR 1910.1030)

The OSHA Bloodborne Pathogen regulation requires that employers provide appropriate PPE at no cost to the employee when it is “reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials may result from the performance of an employee’s duties.”

The OSHA standard does not mandate or recommend any specific testing for PPE against BBP. It is misleading to claim that any garment meets the requirements

of the OSHA BBP regulations under all conditions. The selection of the proper garment depends on the exposure conditions. Protection from BBP and other biohazards requires additional PPE in addition to garments that should be identified by completing a comprehensive hazard risk assessment.

ASTM F1670 – Synthetic Blood Penetration Test Method

A specimen is subjected to synthetic blood at a prescribed pressure for a period of time. Test liquid is forced against fabric being tested in a pressurized cell. If liquid droplets are seen on the outside of the test fabric, the material has failed the test.

ASTM F1671 – Bacteriophage Penetration Test Method

A specimen is subjected to a liquid medium containing a viral surrogate at a prescribed pressure for a specified period of time. The test liquid is forced against the fabric being tested in a pressurized cell. An assay is used to identify penetration of the viral surrogate even if liquid penetration is not visible.

ASTM F1670 is often used as a screening test for ASTM F1671. Both methods utilize an arbitrary value for applied pressure (2 psi) that is not substantiated in actual end-use settings. Typically, garment seams and closures are not tested even though these components generally offer less barrier protection than the fabric.

AATCC 127 – Hydrostatic Pressure (Water Resistivity)

A fabric is tested to measure the resistance to the penetration of water under hydrostatic pressure.

AATCC 42 – Impact Penetration (Water)

A fabric is tested to measure the resistance to the penetration of water by impact.

AAMI PB70 – Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities

There are four performance levels:

- AAMI Level I: Water Impact (AATCC 42) \leq 4.5g
- AAMI Level II: Water Impact (AATCC 42) \leq 1.0g; Hydrohead (AATCC 127) \geq 20cm
- AAMI Level III: Water Impact (AATCC 42) \leq 1.0g; Hydrohead (AATCC 127) \geq 50cm

- AAMI Level IV: Pass ASTM F1671 for surgical gowns, isolation gowns and other protective apparel

European test methods

EN 14126 – Performance requirements and test methods for protective clothing against infective agents

The ability of a protective garment to protect users against infective agents, such as bacteria, viruses and fungi is measured. EN 14126 comprises the ISO 16603 and ISO 16604 tests.

There are different types and purposes of protective clothing under EN 14126:

- Type 3-B: Protection against pressurized liquids
- Type 4-B: Protection against sprayed liquids
- Type 5-B: Protection against dusts and particles
- Type 6-B: Protection against light liquid splash

ISO 16603 – Resistance to penetration by blood and body fluids

Clothing materials are tested using synthetic blood to measure the penetration resistance to blood and body fluids.

ISO 16604 – Resistance to penetration by bloodborne pathogens

Clothing materials are tested to measure the penetration resistance by bloodborne pathogens using Phi-X174 bacteriophage.



DuPont fabric

Test methods for protective apparel



ProShield® 50 ProShield® 70 Tyvek® 400 Tyvek® 500 Tyvek® 500 HV Tyvek® 600 Tyvek® 800 Tychem® 2000 Tychem® 4000 Tychem® 5000 Tychem® 6000

Test Method	ProShield® 50	ProShield® 70	Tyvek® 400	Tyvek® 500	Tyvek® 500 HV	Tyvek® 600	Tyvek® 800	Tychem® 2000	Tychem® 4000	Tychem® 5000	Tychem® 6000
ASTM F1670	✓	✓					✓	✓	✓	✓	✓
ASTM F1671	✓	✓					✓	✓	✓	✓	✓
AATCC 127	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
EN 14126 Type 6-B				✓	✓	✓	✓				
EN 14126 Type 5-B				✓	✓	✓	✓				
EN 14126 Type 4-B						✓	✓				
EN 14126 Type 3-B							✓				

Comparison within the DuPont portfolio: ✓ Acceptable for use
(Blank) Not recommended

Passing results for ProShield® 50 and ProShield® 70 according to ASTM F1670 and ASTM F1671 are based on fabric testing only and do not include seam performance. Passing results for Tyvek® 800, and Taped Seam Tychem® 2000, Tychem® 4000, Tychem® 5000, and Tychem® 6000 garments according to ASTM F1670 and ASTM F1671 are based on testing of both the fabric and taped seams.

As of January 2023, all DuPont Personal Protection products are manufactured under specifications that exclude components containing natural rubber latex. Tyvek® 500, Tyvek® 600 and Tyvek® 800 styles made before January 2023 contain natural rubber latex, which may cause allergic reactions in some sensitized individuals. Anyone who begins to exhibit an allergic response during the use of DuPont products should immediately cease using these products and should report it to DuPont at +1 (888) 439-2988 so that an investigation can be initiated.

All DuPont Personal Protection products are manufactured under specifications that do not contain silicone, with some exceptions. Tyvek® friction-coated shoe covers or Tyvek® garments with friction-coated shoe covers might contain silicone. This includes styles TY122, TY121, FC450 and FC454. Tychem® 6000 AL styles TF630 and TF640T contain a silicone valve diaphragm. End users who are consuming these styles and who have concerns about silicone contamination should conduct their own testing to ensure they are suitable for their application(s).

Garments should have slip-resistant or anti-slip materials on the outer surface of boots, shoe covers or other garment surfaces in conditions where slipping could occur. Some Tychem® garments have attached socks made of the garment material. These attached socks must be worn inside protective outer footwear and are not suitable as outer footwear. These attached socks do not have adequate durability or slip resistance to be worn as the outer foot covering.

This information is based upon technical data that DuPont believes to be reliable. It is subject to revision as additional knowledge and experience become available. It is the user's responsibility to determine the level of toxicity, and the proper personal protective equipment needed. The information set forth herein reflects laboratory performance of fabrics, not complete garments, under controlled conditions. 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, DUPONT DE NEMOURS, INC. AND ITS AFFILIATES 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 THESE PRODUCTS AND INFORMATION. This information is not intended as a license to operate under or a recommendation to infringe any trademark, patent or technical information of DuPont or other persons covering any material or its use.

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