Photo: EU Humanitarian Aid and Civil Protection

CLOTHING TO PROTECT AGAINST INFECTION

Strict medical control and the protection of those who come into contact with biological agents are fundamental to the prevention of infection and the spread of germs. Accordingly, and as defined by European legislation, there are special requirements for the clothing material used to protect against infective agents. An evaluation of the performance of protective coveralls against these criteria, as part of the overall risk assessment, can assist in selecting the right personal protective equipment to minimise the risk of infection.

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CONTENT

1. INTRODUCTION

Strict medical infection control is essential for preventing the spread of highly infectious diseases – and it is mainly the lack of such strict control in the countries most affected by the recent Ebola outbreak that has been responsible for its severity. In countries with high standards of public healthcare, the risk of transmission is generally considered significantly lower.

The use of personal protective equipment is an essential element of infection control for people responsible for care, treatment, transport, preventive measures and decontamination, not only for their own safety, but also for that of their environment.

In this booklet, you will find useful information on the performance of our protective suits when handling biological agents.

2. PROTECTION WHEN HANDLING BIOLOGICAL AGENTS

Whether in agriculture, the food industry, waste separation and recycling facilities, sewer systems or in the emergency services sectors, if workers come into contact with biological agents, safe and reliable protective clothing is essential to prevent infections and the spread of germs.

What are biological agents?

A comprehensive definition can be found in EU directive 2000/54/EC referring to the protection of workers from risks related to exposure to biological agents at work. "Biological agents" refers primarily to micro-organisms such as bacteria, viruses and fungi. According to this directive, it also refers to biological materials, including those which have been genetically modified, as well as agents. What is important is that these substances can be pathogenic, sensitising or toxic. Biological agents have the ability to adversely affect human health in a variety of ways, ranging from relatively mild allergic reactions to serious medical conditions, including death.

What are the biological agent risk groups?

The aforementioned directive requires the classification of biological agents into four risk groups, according to their level of risk of infection:

Risk Group 1:
Biological agents unlikely to cause sickness in humans.

Risk Group 2:
Biological agents that could cause sickness in humans and represent a danger to employees; substance dispersal among the population is unlikely; effective preventive measures or treatment is normally possible.

Risk Group 3:
Biological agents that can cause severe illness in humans and represent a serious risk for employees; a risk of dispersal among the population may occur, but effective preventive measures of treatment are normally possible.

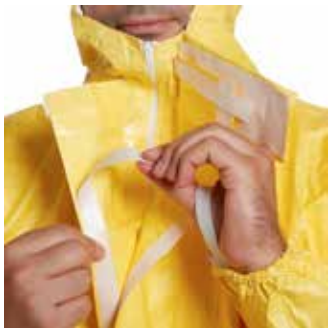
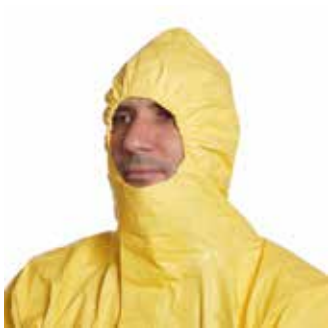
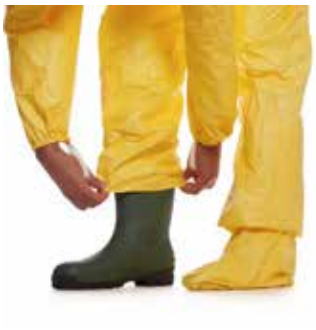
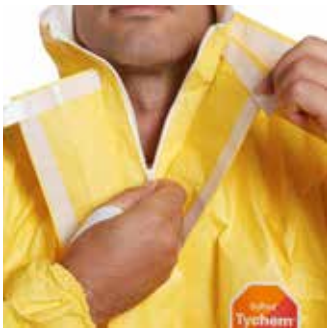
Risk Group 4:
Biological agents that cause severe illness in humans and represent a serious risk for employees; the risk of dispersal among the population is high under some circumstances; effective preventive measures or treatment are not normally possible.

A comprehensive classification of biological agents into risk groups is given in the annex of the EU directive 2000/54/EC.

How do we come into contact with biological agents?

A wide variety of activities can bring you into contact with bacteria, viruses or fungi, for example:

1. The manufacture and use of biological agents (this includes, for example, isolation, production, propagation, use, processing, filling, transferring, mixing, supply and disposal).
2. Occupational contact with people, animals, plants, biological products, objects and materials (if this involves the release of biological agents and contact with them).

Where do biological substances occur, what are they, and what diseases can they trigger?

Sector	Biological substances	Possible diseases
Agriculture	Moulds	Allergies
	Bacteria *(actinomycetes)*	Farmer's lung *(EAA)*
	Microorganisms *(e.g. Erwinia herbicola)*	Organic dust toxic syndrome *(humidifier fever)*
	Bacteria *(e.g. Listeria monocytogenes)* Pathogens *(e.g. Coxiella burnetii)* Fungi *(e.g. Dermatophytes)*	Zoonotic diseases *(sickness transmitted from animals to humans)*, e.g. Q fever, listeriosis or skin mycoses
Handling of veterinary waste (e.g. waste separation/recycling facilities, composting facilities)	Moulds *(e.g. Aspergillus fumigatus)*	Allergies Aspergillosis, aspergilloma
	Bacteria *(Actimomycetes)*	Extrinsic allergic alveolitis *(EAA)*
	Gram-negative bacteria	Organic dust toxic syndrome *(humidifier fever)*
	Enteric viruses, enteric bacteria	Infections *(e.g. gastroenteritis)*
Wastewater treatment plants, sewer system work	HAV virus	Hepatitis A
	Salmonella	Salmonellosis
	Echo, rota virus	Enterovirosis *(virus infection)*
	Bacteria *(e.g. Leptospirosis)*	Leptospira interrogans
Hospitals, healthcare, laboratories, police, emergency services	Ebola, Lassa	Fevers
	HIV virus	AIDS
	Bordetella pertussis	Whooping cough
	Mycobacterium tuberculosis	Tuberculosis
	HBV virus	Hepatisis B
Food industry	Moulds/yeast	Allergies, skin irritations
	Bacteria	
	Endotoxins	Organic dust toxic syndrome *(ODTS)*

Source : BG and OSHA documentation

3. PROTECTIVE CLOTHING ACCORDING TO EN 14126:2003

According to the EU directive 2000/54/EC on Biological Substances, employers are obliged to make suitable protective clothing available to their employees. What clothing provides protection against biological agents?

The European standard EN 14126* defines performance requirements for clothing materials to protect against infective agents. The test methods specified in this standard focus on the medium containing the microorganism; such as liquid, aerosol, or solid dust particle. Due to the heterogeneity of micro-organisms, the standard does not define performance criteria for specific types of micro-organisms. This subtle point needs to be considered in the risk assessment and with reference to the risk group of the infective agent itself. This European standard only refers to "materials" itself, with no infective-agent performance requirements on the seam. Since viruses, bacteria and spores are small enough to penetrate through the openings of sewn seams, suits with over-taped seams are recommended.

Protective suits made of EN 14126 compliant fabrics must also meet the whole suit requirements specified in the relevant chemical protective clothing "Type" standard (see table 1). They must be CE Certified as Category III and can be identified by the biohazard pictogram. The clothing Types to protect against biological agents are broken down as follows:

Type	Description	Relevant standard
1a-B, 1b-B, 1c-B	Gas-tight	EN 943-1:2002, EN 943-2:2002
2-B	Non-gas-tight	EN 943-1:2002, EN 943-2:2002
3-B	Protection against pressurised liquid chemicals	EN 14605:2005 + A1:2009
4-B	Protection against liquid aerosols (spray tight)	EN 14605:2005 + A1:2009
5-B	Protection against airborne solid particulates	EN ISO 13982-1:2004 + A1:2010
6-B	Limited protection against liquid chemicals (light spray)	EN 13034:2005 + A1:2009

Table 1: Protective clothing Types referenced in EN 14126:2003

EN 14126:2003 comprises the following material tests, conducted on garment fabrics only**:

Screening pressure test: Resistance to penetration by blood and body fluids using synthetic blood – ISO 16603

The synthetic blood used for this test is a mixture of cellulose, colouring, buffer solution and stabilising agents. This is referred to as a "screening-test" and is used to predict the pressure at which the subsequent test, using bacteriophage contaminated media, can be expected to penetrate through the material.

Class	Exposure pressure [kPa]
6	20
5	14
4	7
3	3,5
2	1,75
1	0

Table 2: Classification according to EN 14126 of resistance to penetration by blood and body fluids using synthetic blood. Pressurisation duration: 5 min

Resistance penetration by blood-borne pathogens using a bacteriophage ("virus" penetration simulation) – ISO 16604

The "virus" test and classification runs along the same lines as ISO 16603, the only difference being that contaminant used is a bacteriophage (Phi-X-174) instead of synthetic blood. A bacteriophage is a virus that infects and replicates within a bacterium. The bacteriophage (Phi-X-174) serves as a surrogate to simulate viruses that are pathogenic to humans. It is similar to HCV in size and shape, but also may serve as a surrogate for HBV and HIV. Inference for protection from other pathogens must however be assessed by experts on a case-by-case basis.

Resistance to penetration by biologically contaminated liquids (wet bacterial penetration) – ISO 22610

This standard sets out the procedure for testing a material's resistance to wet bacterial penetration. The test method involves superimposing the bacterial-contaminated donor material onto the test material and subjecting it to mechanical rubbing. Table 3 shows six classes, as defined in the standard, with their corresponding breakthrough times, indicating the point at which the bacteria demonstrably penetrate the barrier material.

** Performance requirements and test methods for protective clothing against infective agents*
*** Typically, seams and closures are not tested even though these components generally offer less barrier protection than the fabric.*

Class	Bacterial penetration breakthrough time [min]
6	> 75
5	> 60
4	> 45
3	> 30
2	> 15
1	≤ 15

Table 3: Classification according to EN 14126 of resistance to penetration by contaminated liquids

Resistance to penetration by biologically contaminated liquid aerosols – ISO/DIS 22611

When testing the barrier effect against biologically contaminated aerosols, a bacterium solution (Staphylococcus Aureus) suspended in an aerosol is sprayed onto both an unprotected cellulose-nitrate membrane and one covered with the test material (the pore size of the membrane is approx. 0.45 µm). Both membranes are subsequently analysed to establish their bacterial load. In order to classify the results, the penetration ratio (ratio of the load of the unprotected cellulose-nitrate membrane to the load of the membrane protected with the test material) is calculated and given in log units (Table 4).

Class	Penetration ratio without/with test material [log]
3	> 5
2	> 3
1	> 1

Table 4: Classification according to EN 14126 of resistance to penetration by biologically contaminated aerosols

Note on the reading of these results: By means of an example, according to this classification, a Class 1 barrier material allows the penetration of up to 100 of the 1,000 bacteria on the surface sprayed with the aerosol (i.e. 10% of the bacteria). Class 2 materials of the same surface size allow 10 of the 1,000 through (1%) and material in the highest class (3) allow the penetration of just 1 of 100,000 bacteria (0.001%).

NB: This test has since been withdrawn (2007). We continue to cite these values as EN 14126 :2003 references this test method.

Resistance to penetration by biologically contaminated solid particles (dry microbial penetration) – ISO 22612

For the barrier test against biologically contaminated solid particles, a pre-sterilised material specimen is fixed in the test apparatus and administered with contaminated (Bacillus Subtilis) talcum powder. An agar plate is placed underneath. During the test, this test assembly is shaken. The particles which penetrate the material are analysed after incubation of the agar plate, whereby a non-contaminated test specimen is run as a control. The results (mean values from 10 single results at a given time) are measured in penetration log units (Table 5).

Class	Penetration ratio with/without test material [log]
3	≤ 1
2	≤ 2
1	≤ 3

Table 5: Classification according to EN 14126 of resistance to penetration by biologically contaminated solid particles

NB: When looking at this classification it becomes apparent that, based on the comparatively small gauging surface used for the test, i.e. 20 x 20 cm², a suit material can allow an average of 9.99 CFU to penetrate and still achieve the highest class of protection, i.e. Class 3. Regarding the fineness of dust, this standard only stipulates that 95% of the contaminated talcum powder used must have particle sizes smaller than 15 µm. It does not lay down any specifications regarding the distribution of particle sizes.

4. PROTECTIVE COVERALLS BY DUPONT PERSONAL PROTECTION

DuPont Personal Protection offers protective suits which cover all four risk groups as well as Types 3 to 6. Depending on the form of biological agent, the levels of exposure, the nature of the work and the risk of infection, the barrier performance of the fabric to the relevant infective agent test(s) should be considered. The type of seam and the material's mechanical robustness also needs to be taken into consideration. For instance, in the case of viruses, such as Ebola, performance with regard to their resistance to penetration by blood-borne pathogens (ISO 16604) is key.* The comparative performance of DuPont protective garments is shown in the table on the following pages.

Simply wearing protective clothing will not guarantee protection however. The protective effect of the suits can only be ensured if the clothing is put on and taken off in the correct way and if correct working procedures are followed. For example, a suit being taken off incorrectly may result in the wearer becoming contaminated. A contamination risk also exists for people involved in the disrobing and disinfection of the wearer, and an adequate level of protection is essential for those engaged in such activities.

DuPont can provide information support on the subject of donning and doffing, including a video (available at www.chemicalprotection.dupont.co.uk) that can be used for training personnel.

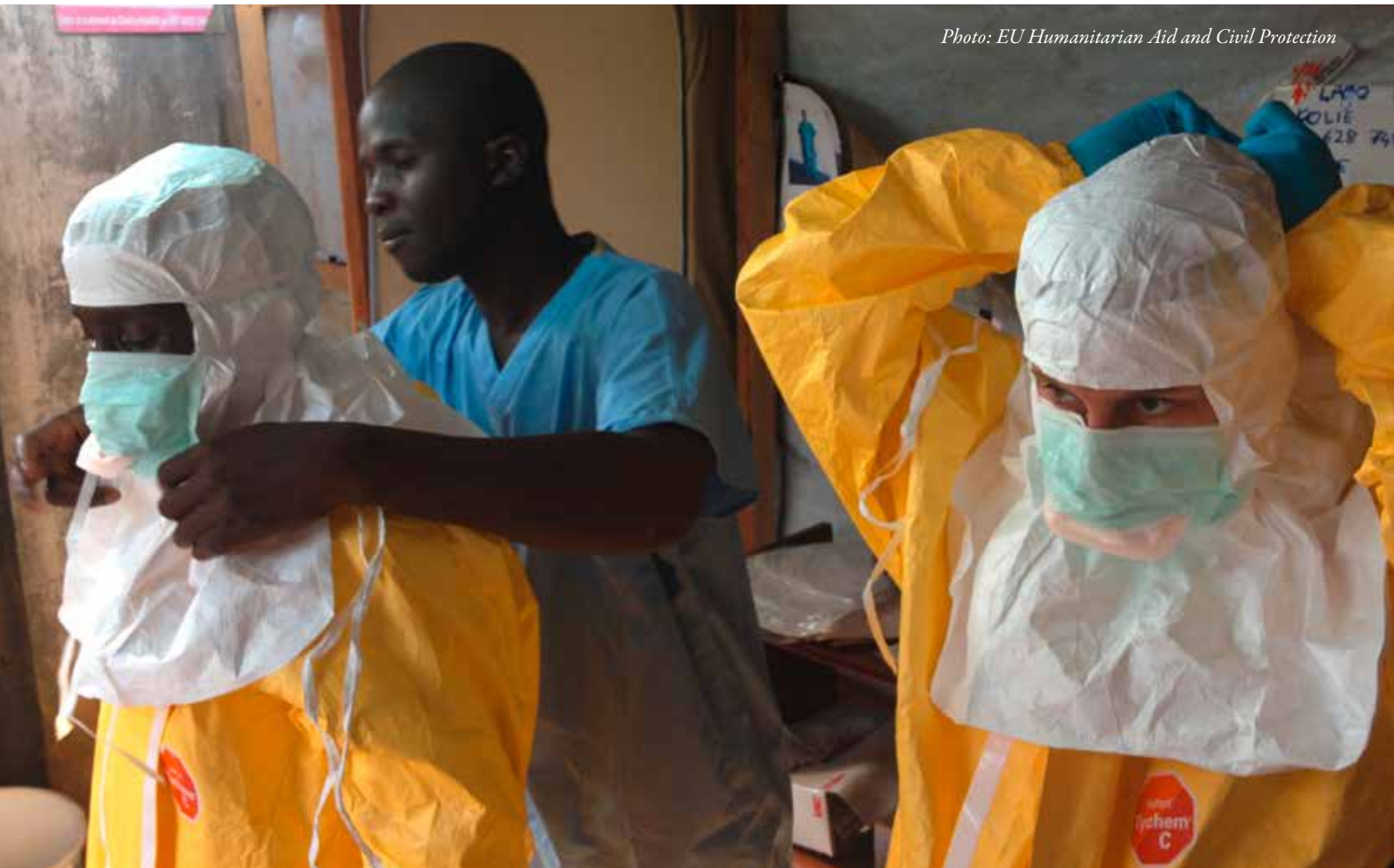


Photo: EU Humanitarian Aid and Civil Protection

Comparative performance of DuPont protective garments

Garment model			 DuPont™ Tyvek® Classic Xpert	 DuPont™ Tyvek® Classic Plus
Protection type			Type 5&6	Type 4, 5&6
Seam construction			Sewn	Stitched and over-taped
Breathability			Air and water vapour permeable	Air and water vapour permeable
Risk groups**			1	1, 2
EN 14126 – Performance requirements and test methods for protective clothing against infective agents				
Screening pressure test: Resistance to penetration by blood and body fluids using synthetic blood – ISO16603	Class	Exposure pressure [kPa]		
	6	20		
	5	14		
	4	7		
	3	3,5	3	3
	2	1,75		
	1	0		
Resistance penetration by blood-borne pathogens using a bacteriophage ("virus" penetration simulation) – ISO 16604 Procedure D	Class	Exposure pressure [kPa]		
	6	20		
	5	14		
	4	7		
	3	3,5		
	2	1,75		
	1	0	No classification	No classification
Resistance to penetration by biologically contaminated liquids (wet bacterial penetration) – EN ISO 22610	Class	Bacterial penetration breakthrough time [min]		
	6	> 75		
	5	> 60		
	4	> 45		
	3	> 30		
	2	> 15		
	1	≤ 15	1	1
Resistance to penetration by biologically contaminated liquid aerosols – ISO/DIS 22611	Class	Penetration ratio without/with test material [log]		
	3	> 5		
	2	> 3		
	1	> 1	1	1
Resistance to penetration by biologically contaminated solid particles (dry microbial penetration) – ISO 22612	Class	Penetration ratio with/without test material [log]		
	3	≤ 1		
	2	≤ 2		
	1	≤ 3	1	1

** Please note: Fabrics are tested using recognized procedures to determine the level of barrier against proxy materials for blood borne pathogens; they*

*** DuPont suggestion based on garment barrier performance. Please note that selection of the appropriate garment remains the responsibility of the e*

 DuPont™ Tyvek® 800 J	 DuPont™ Tychem® C	 DuPont™ Tychem® C2	 DuPont™ Tychem® 4000 S	 DuPont™ Tychem® F	 DuPont™ Tychem® F2
Type 3, 4, 5&6	Type 3, 4, 5&6	Type 3, 4, 5&6	Type 3, 4, 5&6	Type 3, 4, 5&6	Type 3, 4, 5&6
Stitched and over-taped	Stitched and over-taped	Stitched and over-taped	Stitched and over-taped	Stitched and over-taped	Stitched and over-taped
Water vapour permeable	Impermeable	Impermeable	Impermeable	Impermeable	Impermeable
1, 2, 3	1, 2, 3, 4	1, 2, 3, 4	1, 2, 3, 4	1, 2, 3, 4	1, 2, 3, 4
6	6	6	6	6	6
	6	6	6	6	6
4					
6	6	6	6	6	6
3	3	3	3	3	3
3	3	3	3	3	3

are not tested against specific viruses.
nd-user and must be made following a thorough hazard assessment of the work tasks and the environment.

Further information on the above garments and their barrier performance can be found at

www.safespec.dupont.co.uk

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