

DuPont™ Tyvek® Isoclean® Product Information

Protective coverall for use in cleanrooms

Application area and properties

- **Maximum protection and comfort:** Type-tested and certificated as complex PPE¹⁾ category III; chemical protective clothing, protection against infective agents. Type 5-B and 6-B. Coverall with thumb loops, elasticated wrists and ankles, front zipper closure, storm flap. Bound internal seams.
- **Application range:** Cleanroom coverall, low in particles, suitable for ISO class 4/5 and GMP class A/B. Sterilized, individually and double wrapped. Coverall for handling chemicals, oils and biological agents (incl. viruses).
- **Protective properties:** Reliable protection against numerous water based inorganic chemicals at low concentration and other hazardous particles (category III, type 5-B) protection against infective agents. Protection against radioactive particles (EN 1073-2).
- **Directions for use:** Keep away from flames or intensive heat.
- **Change interval:** Maximum wear in accordance with chemical substances permeation²⁾ list, for biological hazards a maximum of one working shift, in case of visible contamination immediately! Single use only!
- **Before use:** Check for any damage! Do not use damaged coveralls!
- **Disposal:** Waste requiring supervision (waste code: 18 01 04*)³⁾ in accordance with (2000/532/EC); collect and dispose of waste separately!

1): Personal protective equipment. 2): Dependent on the utilized chemicals / CMR-drugs or biological materials. 3): Any waste marked with an asterisk (*) is considered hazardous waste pursuant to Article 1(4), first indent of Directive 91/689/EEC on hazardous waste.

Versions

Size	Chest girth (cm)	Body height (cm)	Nos. per unit	Order No.: (sterile)
S	84 – 92	150 – 185	25	100118
M	92 – 100	168 – 176	25	100114
L	100 – 108	174 – 182	25	100115
XL	108 – 116	180 – 188	25	100116
XXL	116 – 124	186 – 194	25	100117
XXXL	124 - 132	190 - 195	25	100287



Material properties

Material	Tyvek® „Impervious Technology“
Material weight	65 g/m ²

Protection against mechanical properties

Mechanical properties of material tested in accordance with DIN EN 14325:2004. Coding with regard to the performance classes as follows:

Requirements	Performance class
Abrasion resistance (1-6) acc. EN 530	1
Puncture resistance (1-5) acc. EN 863	1
Tensile strength (1-5) acc. ISO 13934-1	1
Flex cracking (1-6) acc. ISO 7854	6
Trapezoidal tear strength (1-5) acc. ISO 9073-4	1

Protection against chemical hazards

Permeation⁶⁾ to EN ISO 6530

Chemical	Penetration index - EN Class	Repellency index - EN Class
Sulphuric acid (30 %)	3	3
Sodium hydroxide (10 %)	2	2

Permeation⁶⁾ tested in accordance with EN ISO 14325

Breakthrough times⁷⁾ [min] / performance classes⁸⁾ (1-6) were established for the following chemicals:

Tested chemicals	Breakthrough time [min]	Performance class
Carmustine (3,3 mg/ml)	> 480	6
Cisplatin (1 mg/ml)	> 480	6
Doxorubicin HCL (2 mg/ml)	> 480	6
Fluorouracil, 5 (10 mg/ml)	> 480	6



Ganciclovir (3 mg/ml)	> 480	6
Irinotecan (20 mg/ml)	> 480	6
Mitomycine C (0,5 mg/ ml)	> 480	6
Oxaliplatin (5 mg/ml)	> 480	6
Paclitaxel (6 mg/ml)	> 480	6
Sodium chloride (9 g/l)	> 480	6
Thiotepa (10 mg/ml)	> 480	6
Vinorelbin (0,1 mg/ml)	> 480	6
Sodium hydroxide (40 %)	> 480	6
Hydrogen peroxide (10 %)	> 480	6
Hydrochloric acid (16 %)	> 480	6
Nitric acid (10 %)	> 480	6
Sulphuric acid (30 %)	> 480	6
Sulphuric acid (50 %)	> 60	3
Sodium hypochlorite	> 480	6
Potassium hydroxide (40 %)	> 480	6
Phosphoric acid (50 %)	> 480	6

6): Movement of a chemical through a material on a molecular level. 7): At a permeation rate of 1 µg/min*cm² 8): The performance class does not reflect the actual duration of protection at the workstation, as temperature and abrasion may have an effect on these!

Protection from infectious agents

Penetration⁹⁾ tested in accordance with EN 14126 fulfilled. Test results as follows:

Resistance to penetration by blood and body fluids in acc. to ISO 16603.

Performance class (1-6)

3

Resistance to penetration of pathogens, which are blood transmitted using the virus Phi-X174 to ISO 16604.

Performance class (1-6)



no classification

Resistance to wet bacterial penetration in accordance with EN ISO 22610.

Performance class (1-6)

1

Resistance to penetration of biologically contaminated aerosols in accordance with ISO/DIS 22611.

Performance class (1-3)

1

Resistance to dry microbial penetration in accordance with ISO 22612.

Performance class (1-3)¹⁰⁾

1

9): Entry of solid, liquid or gaseous agents through macroscopic holes (flaws, seams).

10): The performance class does not reflect the actual period of protection at the workplace!

Care instructions

- Single use item, see instructions for use leaflet

CE-marking

In accordance to the PPE regulation EU 2016/425 for complex PPE category III, on the basis of DIN EN 13034:2005 +A1:2009; EN 14126:2003; EC-type test and control measures by the notified body „0598“. **Documented by EC type test certificate no. 0598/PPE/22/3281.** The EC-declaration of conformance and the EC-Type test certificate can be downloaded at www.berner-safety.de

Notified body “0598”

SGS Fimko Oy, Takomotie 8, FI-00380 Helsinki, Finland.

Quality management system

Our **quality management system** is **tested and certified** by TÜV Management Service GmbH (a certification body accredited by the German Accreditation Council) in accordance with DIN EN ISO 9001:2015. Regular **audits and production site inspections** guarantee the quality of our products.



Storage and transport conditions

- Dark (protect from direct UV light and sunlight)
- Cool (+15 to +25°C)
- Dry
- No contact with pointed and/or sharp objects

Shelf life

- Sterile version: 5 years from the date of manufacture

Manufacturer

DuPont Personal Protection, L-2984 Luxembourg

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