PRODUCT INFORMATION

Protective overall DuPont™ Tyvek® Isoclean®

Protective overall for use in cleanrooms

Area of application and properties

- Maximum protection and wearing comfort: Type-tested and certificated as complex PPE category III; chemical protective clothing, protection against infective agents. Type 5-B and 6-B. Overall with thumb loops, elasticated wrists and ankles, front zipper closure, storm flap. Bound internal seams.
- Application range: Cleanroom overall, low in particles, suitable for ISO class 4/5 and GMP class A/B. Sterilised, individually and double wrapped. Overall for handling chemicals, oils and biological agents (incl. viruses).
- Protective properties: Reliable protection against numerous waterbased 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 permeation list, for biological hazards a maximum of 1 working shift, in case of visibile contamination immediately! Single use only!
- Before use: Auf Beschädigungen prüfen! Beschädigte Schutzoveralls nicht verwenden!
- Disposal: Waste requiring supervision (waste code: 18 01 04*) in accordance with 2000/532/EC); collect and dispose of waste separately!

Versions

Size	Chest girth (cm)	Body height (cm)	No. per pack	Order No.: (sterile)
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

Material properties

Material	Tyvek® "Impervious Technology"
Material weight	65 g/m²

Protection against mechanical hazards

Mechanical hazards tested to EN 14325:

Tests	Result	
Abrasion resistance to EN 530	1	
Trapezoidal tear resistance to ISO 9073-4	1	
Tensile strength to ISO 13934-1	1	
Puncture resistance to EN 863	1	
Flex cracking resistance to ISO 7854	6	



^{1):} Dependent on chemical / CMR-pharmaceutical drug use. 2): Any types of waste marked with (*) is hazardous waste in accordance to the German § 41 of the KrW-/AbfG.

Resistance to chemical hazards

Protection against chemical hazards: Permeation to EN ISO 6530	
Sodium hydroxide (10%)	2
Sulphuric acid (30%)	3
Resistance to biological hazards	
Resistance to penetration by blood and body fluids using synthetic blood (ISO 16603)	3/6
Resistance to penetration by contaminated liquids	1/6
Resistance to penetration by biologically contaminated aerosols	1/3
Resistance to penetration by contaminated solid particles(ISO/ DIS 22611)	1/3

Quality management system

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 9001:2008. Regular audits and production site inspections guarantee the quality of our products.

Notified body "0598"

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

Storage and transport conditions

- Dark (protect against direct UV and sun light)
- + Cool (+15 to +25°C)
- Dry
- No contact with pointed or sharp items

Care instructions:

+ Single use item, see instructions for use leaflet

Shelf life

Sterile, 5 years from date of manufacture

Distributor

Berner International GmbH, Werner-von-Siemens-Str. 19, 25337 Elmshorn, Germany Tel: +49 4121 43560, Fax: +49 4121 435620

info@berner-safety.de, www.berner-safety.de

