

PRODUCT INFORMATION

cleo® saphir

Protective overshoe for use with cytostatic & biological substances

Application area and properties

- + **Maximum protection and comfort:** Type-tested and certified as complex PPE¹⁾ (category III); chemical protective clothing type PB [4], protective clothing against infection type PB [4]-B; partial body protection. Optimal personal and product protection (sterile version); elasticated cuffs at the leg ends; comfortable to wear; material is latex-free, low in lint with low particle generation; sterile and unsterile version.
- + **Area of application:** Protective overshoe for handling CMR²⁾ drugs (e.g. cytostatic and virostatic agents) and biological agents³⁾ (e.g. bacterial and viruses).
- + **Protective barrier:** Liquid-impervious coating. In compliance with EN 14126:2003 a high barrier function of the coated material against bacteria and viruses can be assumed.
- + **Protection capacity:** Protection from all CMR drugs or chemicals cannot be guaranteed! In case of exposition to biological hazardous materials, which do not correspond to the degree of imperviousness of the protective clothing, biocontamination of the wearer is possible.
- + **Directions for use:** Always wear with the coated side on the outside and the seam pointing downwards. Keep away from open flames and heat sources.
- + **Change interval:** Daily, i.e. use up to a maximum of 8 hours⁴⁾; in case of visible contamination immediately! Single use only!
- + **Before use:** Check for any damage! Do not use damaged sleeve covers!
- + **Disposal:** Waste requiring supervision (waste code: 18 01 04 in accordance with 2000/532/EC); in case of heavy contamination, waste requiring special supervision⁵⁾ (waste code: 18 01 08*⁶⁾ or 18 01 03*⁷⁾ in accordance with 2000/532/EC); collect and dispose of waste separately!

¹⁾: Personal protective equipment. ²⁾: Carcinogenic mutagenic toxic to reproduction. ³⁾: Microorganisms, including genetically altered microorganisms, cell cultures and human endoparasites, which could cause infections or allergies or have toxic effects. ⁴⁾: Dependent on the utilized chemicals / CMR-drugs or biological materials. ⁵⁾: 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. ⁶⁾: Cytotoxic and cytostatic drugs. ⁷⁾: Waste, whose collection and disposal is subject to special requirements in view of the prevention of infection.

Types

Size	Universal
Item No. (non-sterile) 20 pairs	12 55 01
Item No. (sterile) 15 pairs	12 55 02
Colour	blue/white

Material properties

Material	Spun polypropylene
Material properties	Latex-free
Material weight	42 g/m ²
Liquid-tight coating	Polyethylene
Coating thickness	approx. 25 µm
Total weight of gown	30 g ± 5 g
pH-value nonwoven with coating & knitted cuffs	6.2

MAK amines / AZO dyes

not detectable

Protection from mechanical hazards

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 530:2010	1 (visual inspection)	
Puncture resistance (1-5) acc. EN 863:1995	1	
Seam strength (1-5) gem. ISO 13934-1:1999	3	
Tensile strength (1-5) acc. ISO 13935-2:1999	2	
Flex cracking (1-6) acc. ISO 7854:1997	2	
Trapezoidal tear strength (1-5) acc. ISO 9073-4:1997	Longitudinal: 4	Transverse: 3

Anti-slip property:

The resistance to slipping of sole was tested in accordance to DIN 4843-100:1993. Overshoes are appropriate for the designated range of use. Powder-free acc. TRGS 540

Protection from chemical hazards

Permeation¹⁾ tested in accordance with DIN EN 16523-1:2015.

Breakthrough times²⁾ [min] / performance classes³⁾ (1-6) were established for the following chemicals:

Chemical	Breakthrough time [min]	Performance class
Seam testing carmustine (3.3 mg/ml)	> 480	6
Carmustine (3.3 mg/ml)	> 480	6
Cisplatin (1.0 mg/ml)	> 480	6
Cyclophosphamide (20.0 mg/ml)	> 480	6
Etoposide (20.0 mg/ml)	> 480	6
5-Fluorouracil (50.0 mg/ml)	> 480	6
Gemcitabine (38.0 mg/ml)	> 480	6
ThioTEPA (10.0 mg/ml)	> 480	6
NaOH 30%	> 480	6
Formaldehyde 4%	> 480	6
Isopropanol 70%	> 480	6

¹⁾: Movement of a chemical through a material on a molecular level. ²⁾: At a permeation rate of 1 µg/min·cm²

³⁾: The performance class does not reflect the actual duration of protection at the workstation.

Protection from infectious agents

Penetration¹⁾ tested in accordance with EN 14126:2003 fulfilled. Test results as follows:

Resistance to penetration by blood and body fluids in acc. to ISO 16603:2004.

Hydrostatic pressure [kPa]	Performance class (1-6) ²⁾
20 kPa	6

Resistance to penetration of pathogens, which are blood transmitted using the virus Phi-X174 to ISO 16604:2004.

Hydrostatic pressure [kPa]	Performance class (1-6) ²⁾
20 kPa	6

Resistance to wet bacterial penetration in accordance with EN ISO 22610:2006.

Breakthrough time [min]	Performance class (1-6) ²⁾
t > 75	6

Resistance to penetration of biologically contaminated aerosols in accordance with ISO/DIS 22611:2003.

Penetration ratio (log)	Performance class (1-3) ²⁾
log > 5	3

Resistance to dry microbial penetration in accordance with ISO 22612:2005.

Penetration (log of the CFU ³⁾)	Performance class (1-3) ²⁾
Log of CFU < 1	3

¹⁾: Entry of solid, liquid or gaseous agents through macroscopic holes (flaws, seams).

²⁾: The performance class does not reflect the actual period of protection at the workplace! ³⁾: CFU = Colony forming units

Sterilisation

Procedure

Fumigation with ethylene oxide

Care instructions

- + Do not wash
- + Do not iron
- + Do not tumble dry
- + Do not dry clean

CE-marking

In accordance to the PPE regulation EU 2016/425 for complex PPE category III, on the basis of DIN EN 14605:2005 +A1:2009; EN 14126:2003; EC-type test and control measures by the notified body „2797“. Documented by EC type test certificate no. CE 715808. The EC-declaration of conformance and the EC-Type test certificate can be downloaded at www.berner-safety.de.

Notified body "2797"

BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, NL

Quality management system

Our **quality management system** is **tested and certified** by TÜV Management Service GmbH 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 (+5 to +40°C)
 - + Dry (Relative humidity 30-60%)
 - + No contact with pointed and/or sharp objects
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Shelf life

Unsterile version: 5 years from the date of manufacture

Sterile version: 4 years from the date of sterilisation

Distributor

Berner International GmbH, Werner-von-Siemens-Str. 19, 25337 Elmshorn

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