

PRODUCT INFORMATION

Overboots activebreath 2

For cytostatic drugs & biological agents

Application and properties

- + **Maximum protection und comfort:** Type-tested and certified as complex PPE of the highest category III; chemical protective clothing type PB [6]-B, partial body protection. Optimum personal and product protection; liquid-impermeable in the coated foot area, pleasant wearing comfort; overboots with non-slip sole, leg closure with elastic band; additional banding for fixation; sterile and non-sterile design.
- + **Application range:** The protective overshoes protect against contact with CMR¹⁾ drugs. They provide protection against particles, liquids or aerosols type PB [6]-B, with limited protection against liquid chemicals.
- + **Protective barrier:** Liquid impermeable coating with a high barrier function of the coated material against bacteria and viruses.
- + **Protective properties:** Protection against penetration of chemicals and biologically contaminated liquids, limited spray tightness according to EN 13034, tested permeation protection according to the permeation list given here. No guarantee for CMR¹⁾ drugs or chemicals not listed. In case of exposure to biological agents and chemicals, which do not correspond to the level of protection of the protective clothing, permeation of the protective overboots type PB [6]-B may occur.
- + **Carrying note:** Always wear with the coated side facing out. Keep away from flames and heat sources.
- + **Change interval:** Use daily, i.e. max. 8 h²⁾, immediately in case of visible contamination! Single use!
- + **Before use:** Check for any damage! Do not use damaged over boots!
- + **Waste disposal:** Waste requiring supervision (waste code: 18 01 04 acc. to 2000/532/EC), in case of heavy contamination waste requiring special supervision³⁾ (waste code: 18 01 08* or AS 18 02 07*, acc. to 2000/532/EC 18 01 08*⁴⁾; collect and dispose of separately!

¹⁾: Carcinogenic Mutagenic Reproductive Toxic. ²⁾: Dependent on chemicals/CMR drugs used. ³⁾: Waste types marked with (*) in the waste list are hazardous wastes in the sense of § 41 of the KrW-/AbfG. ⁴⁾: Cytotoxic and cytostatic drugs.

Versions

Size	Universal
Item No. (non-sterile) 20 pairs	125550
Item No. (sterile) 25 pairs	125551
Colour	white

Material properties

Material	Spun bonded polypropylene nonwoven
Material weight	69 g/m ²
Liquid-tight coating	Microporous polyethylene
Total length	ca. 45 cm
Total weight of over boots (pairs)	49 g ± 3 g
pH-value	9,4

Protection against mechanical properties

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

Requirements	Performance class	
Abrasion resistance (1-6) gem. EN ISO 530	6	
Puncture resistance (1-5) gem. EN 863	2	
Seam strength (1-5) gem. ISO 13935-2	4	
Flex cracking (1-6) gem. EN ISO 7854	Longitudinal 6	Transverse 6
Trapezoidal tear strength (1-6) gem. EN ISO 9073-4	Longitudinal 3	Transverse 3
Tensile strength (1-5) gem. EN ISO 13934-1	Longitudinal 3	Transverse 2

Protection against chemical hazards

Permeation⁵⁾ tested in accordance with EN 14325 paragraph. 4.12 respectively. DIN EN 6530

Chemical	Breakthrough time [min.]	Resistance
Sulphuric acid 30%	Class 3	Class 3
Sodium hydroxide 10%	Class 3	Class 3
o-Xylene (undiluted)	Class 3	Class 3
1-Butanol (undiluted)	Class 3	Class 3

Permeation⁵⁾ tested in accordance to the European standard EN 16523-1. For the following chemicals the breakthrough times⁶⁾ [min] / performance categories⁷⁾ (1-6) were determined:

Tested chemicals	Breakthrough time [min]	Performance class
Carmustine (3.3 mg/ml)	> 480 min	6
Cisplatin (1.0 mg/ml)	> 120 min	4
Cyclophosphamide (20 mg/ml)	> 120 min	4
3,3'-Diaminobenzidine (1 mg/ml)	> 30 min	2
Etoposide (20mg/ml)	> 480 min	6
Formaldehyde 37%	> 120 min	4
5-Fluorouracile (10.0 mg/ml)	> 120 min	4
Gemcitabine (38.0 mg/ml)	> 240 min	5
Isopropanol 70%	> 30 min	2
Congo- red 1%	> 30 min	2
Sodium hydroxide 10%	> 120 min	4
Paclitaxel (6mg/ml)	> 120 min	4
Sulphuric acid, 30 %	> 60 min	3

ThioTEPA (10.0 mg/ml)	> 120 min	4
Vincristine (1.0 mg/ml)	> 120 min	4

5): Movement of a chemical through a material on a molecular level.

6): At a permeation rate of 1 µg/min.cm²

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

Protection from infectious agents

Penetration⁸⁾ tested in accordance with EN 14126 fulfilled. Test results as follows:

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

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.

Hydrostatic pressure [kPa]	Performance class (1-6) ⁹⁾
20 kPa	6

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

Breakthrough time [min]	Performance class (1-6) ⁹⁾
t > 75	6

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

Penetration ration (log)	Performance class (1-3) ⁹⁾
log > 5	3

Resistance to dry microbial penetration in accordance with ISO 22612.

Penetration ration (log of CFU ¹⁰⁾)	Performance class (1-3) ⁹⁾
Log of CFU < 1	3

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

9): The performance class does not reflect the actual period of protection at the workplace! 10): CFU = Colony forming units

Sterilization

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; type tested on the basis of DIN EN 13688, EN 13034 and EN 14325. EC-type test and control measures by the notified body „0624“. Documented by EC type test certificate no. CE 1002220675-00-00.

The EC-declaration of conformance and the EC-Type test certificate can be downloaded at www.berner-safety.de.

Notified body „0624“

Centrocot Tessile Contoiere e Abbigliamento S.p.A., Piazza S. Anna 2, 21052 Busto Arsizio (VA), Italien

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°C to 40°C)
 - + Dry (relative humidity 30% – 60%)
 - + No contact with pointed and/or sharp objects
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Shelf life

- + Non-sterile version: 5 years
 - + Sterile version: 5 years
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Manufacturer

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

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