

## cleo® care Product information

### Spill proof prep mats for working with cytostatics and biological agents

#### Area of application and properties

For collecting spilled liquids to a limited extent. The non-folded sterile work mats in triple foil outer packaging are designed for safe use in cleanrooms and can be used, for example, to support the safe production of CMR<sup>1)</sup> drugs in cytostatic workbenches under GMP conditions (class A/B) or when handling biological agents<sup>2)</sup> or medical devices.

- **Features:** Gamma-sterilized prep mats for absorbing liquids. Each individual prep mat is double-packed in foil pouches. The bags are easy to open (peel film). For single use only!
- **Protective properties:** No guarantee for all CMR drugs or chemicals!
- **Change interval:** immediately in case of contamination, otherwise after each production cycle or as required.
- **Disposal:** Waste requiring supervision waste code<sup>3)</sup> 18 01 04 in accordance with 2000/532/EG), in the event of heavy contamination, waste requiring special supervision<sup>4)</sup> (waste code: 18 01 08<sup>4)</sup> in accordance with 2000/532/EG); collect and dispose of waste separately!

1): Carcinogenic, mutagenic, toxic to reproduction 2) Microorganisms, including genetically altered microorganisms, cell cultures and human endoparasites, which could cause infections or allergies or have toxic effects 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. 4) Waste, whose collection and disposal is subject to special requirements in view of the prevention of infection.

#### Versions

Itemcode	100288	100289
Dimensions ± 10 %	560 x 410 mm	560 x 410 mm
Number of pieces per carton	100	100
Packaging	Single prep mat double in foil bags, 25 pieces in PE bag, 4 PE bags per box (white carton)	
Sterilized with gamma ray, Dosis	25 kGy	25 kGy
Sterility assurance level	10 <sup>-6</sup>	10 <sup>-6</sup>



## Material and properties

Material	Highly absorbent 3-layer structure for safe preparation and application, low-lint surface for high product protection
Material mesh	Polyethylene, blue
Characteristics	Liquid-permeable, minimises particle release
Material central layer	„Air-laid“-Paper
Characteristics	highly absorbent
Material Underlayer	Polyethylene-Foil, 1 µm
Characteristics	antistatic and impermeable to liquids
Material weight	132 g/m <sup>2</sup> ± 10 g

## Absorbable liquid volume:

Volume measuring in accordance to DIN EN ISO 9073-6:2003-05

Item number	Absolute	Per prep mat
100288	719 ml/m <sup>2</sup>	166 ml
100289	719 ml/m <sup>2</sup> 1	79 ml

## Protection from chemical hazards

**Permeation**<sup>5)</sup> in accordance to EN 374-1:2016+A4:2018; Test method EN 16523-1:2015+A1:2018  
The breakthrough times (min)/performance classes (1-6) were determined for the following chemicals:

Chemikalie	Breakthrough time [min]	Performance class
5-Fluorouracil (50 mg/ml)	> 480	6
Carmustin (3,3 mg/ml)	> 480	6

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



## Sterilization

Procedere: Irradiation with Gamma ( $\gamma$ )-rays

## 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 (+ 5 bis + 40 °C)
- Dry (relative humidity 30 % – 60 %)
- No contact with sharp pointed / or sharp objects

## Shelf life

5 years from the date of manufacture

## Manufacturer

**Berner International GmbH**  
Werner-von-Siemens-Str. 19  
25337 Elmshorn  
T +49 4121 4356-0  
F +49 4121 4356-20  
info@berner-safety.de

[www.berner-safety.de](http://www.berner-safety.de)

