



**1. Read the user instructions carefully before handling or wearing gloves!**

**2. Application, properties, types and disposal**



- **Area of application:** Protective gloves for handling CMR<sup>1)</sup>-drugs (e.g. cytostatics, virostatics), biological substances<sup>2)</sup> and viruses<sup>3)</sup>. cleanroom compatible (sterile version).  
<sup>1)</sup> Cancerogenic, mutagenic, reproductive toxic  
<sup>2)</sup> e.g. bacteria, fungi, parasites  
<sup>3)</sup> to ASTM F 1671-97B

- **Protective properties:** Protection against all CMR drugs, chemicals or biological substances cannot be guaranteed! Use of further substances only after consultation with BERNER.



- **Change interval:** Every 30 min. (in compliance with the BGW (German Federal Association for Health and Welfare) brochure "Cytostatics in health care"), when handling Carmustine or Thiotepa after every manufacturing batch, immediately in case of visible contamination! For single use only!



- **Material:** Polychloroprene, Polymer-coated inside and outside, powder-free, latex-free, pH value: 7, colour: beige.

- **AQL (Acceptable Quality Level):** Safety-related required water permeability test for protective gloves in accordance with EN 374-2 (**water leakage test**). **AQL = 1,0**



- **Dexterity:** Finger dexterity tested in accordance with DIN EN 420:2003, performance level 5 (highest performance level).

- **Before use:** Check for any damage! Do not use damaged gloves!

- **Types:** Available as sterile and non-sterile version. Sterilisation process: Gamma radiation.

		<b>Types</b>						
<b>Size</b>		<b>XS or 6</b>	<b>S or 6½</b>	<b>SM or 7</b>	<b>M or 7½</b>	<b>ML or 8</b>	<b>L or 8½</b>	<b>XL or 9</b>
<b>Item no.</b>	<b>Non-sterile</b> PU =25 Pairs	BI-2010	BI-2012	BI-2014	BI-2016	BI-2018	BI-2020	BI-2022
	<b>Sterile</b> PU =25 Pairs	BI-2011	BI-2013	BI-2015	BI-2017	BI-2019	BI-2021	BI-2023

▪ Disposal:

<b>Substance</b>  	<b>Origin</b>			
	<b>Human</b>		<b>Animal</b>	
	<b>Hazardous potential</b>			
	<b>Low</b>	<b>High</b>	<b>Low</b>	<b>High</b>
<b>CMR drugs</b>	18 01 01	18 01 08*	18 02 03	18 02 07*
<b>Microorganism</b>	18 01 04	18 01 03*	18 02 03	18 02 02*

\* Dangerous or waste needing special supervision.  
 1) Personal protective equipment.  
 2) Cancerogenic mutagenic reproductive toxic.  
 3) Microorganism and infectious agents As in EN 374-1: e.g. bacteria and fungi.



- Collect and dispose of non-contaminated packaging separately!  
 For Germany → "Green dot" the „Dual System Germany GmbH“.

**3. Mechanical hazards**

Mechanical hazards tested in compliance with EN 388:2003.

Performance level coding as follows  
 (Value below 1, Result = "0")



Requirements	Performance level
Abrasion resistance (1-4)	0
Cut resistance (1-5)	0
Tear resistance (1-4)	1
Stab resistance (1-4)	0

**4. Chemical hazards**

Permeation tested in compliance with EN 374-3:2003. The performance level does not reflect the actual period of protection at the work place!



Chemical	Breakthrough time [min]	Performance level
Carmustine	90	3
Cisplatine	>480	6
Cyclophosphamide monohydrate	>480	6
Vincristine	>480	6
Doxorubicin hydrochloride	>480	6
Diethylamine	45	2
40% Sodium hydroxide	75	3
96% Sulphuric acid	45	2

**5. Bacteriological hazards**

Penetration tested in compliance with EN 374-2:2003.



## 6. Viral hazards

ASTM F1671-97b

Penetration test **ASTM F 1671-97b** (Phi X 174) – **Test passed.**

## 7. CE Mark



CE-mark in accordance with the PPE directive 89/686/EEC for complex PPE in category III, based on DIN EN 374 parts 1-3:2003; DIN EN 388:2003; DIN EN 420:2003.

Documented by the EC type test certificate No. PS 09050018. Quality assurance (EC quality assurance system with monitoring): Inspection measures (usually annually) in compliance with Art 11B, 89/686/EEC by the intermediary body BG-PRÜFZERT (0299).

## 8. Notified Body “0299”



Technical Committee for Personal Protective Equipment  
Testing and Certification Body of BG-PRÜFZERT  
Centre for Safety Technology, Zwengenberger Strasse 68  
D-42781 Haan, Germany

## 9. Quality management system

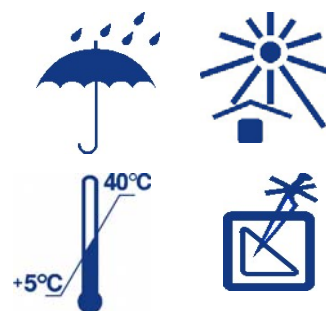


Our quality management system is tested and certified in compliance with DIN EN ISO 9001:2000 by TÜV Management Service GmbH.

## 10. Storage and transport conditions



- Dark (protect from direct UV and sunlight).
- Cool (+5 to +40°C).
- Dry.
- Protect from carbon dioxide in high concentrations.
- No contact with sharp and/or pointed objects.



Size:	Neoprene Protective gloves 3P, Latex-free Non-Sticky
7 1/2	25
Item no.	2016
LOT 811333375	
2008-11	
2011-10	



### 11. Date of manufacture

Numeral 1-4: Jahr, Numeral 5+6: Month



### 12. Use by date

Numeral 1-4: Year, Numeral 5+6: Month (Date of manufacture + 3 years)



### 13. Lot Number

Numeral 1: Year, Numeral 2+3: Month

---

#### 14. Copyright and industrial property right

BERNER INTERNATIONAL GMBH does not accept any liability or guarantee for protective gloves which have been used for any purpose other than that for which they have been designed. Subject to technical and production-related changes. With regard to translations into foreign languages, the German version of the user information is binding.

 and  are registered trade marks of BERNER INTERNATIONAL GMBH.

© BERNER INTERNATIONAL GMBH

Berner International GmbH  
Mühlenkamp 6  
D-25337 Elmshorn  
Phone: +49 4121 43 56 0  
Fax: +49 4121 43 56 20  
info@berner-international.de  
www.berner-international.eu