Protective gloves for cytotoxics and microbiological agents

Area of Application and Features

- **Maximal protection and comfort:** Type-tested and certified as complex PPE[1)] of the highest category III; good grip; good tactile sensitivity.
- **Area of application:** Protective gloves for handling CMR[2)] drugs (e.g. cytostatics) and biological agents[3)].
- **Protective properties:** Protection from all CMR pharmaceuticals cannot be guaranteed!
- **Glove replacement interval**: In accordance with the test results. Single use!
- **Before use:** Check for damage! Do not use damaged gloves!
- **Disposal:** Assignment of waste to European waste codes (EWC) for human or animal health care and / or related research, based on directive 2000/532/EC:

Substance	Origin			
	Human		Animal	
	Hazardous potential			
	Low	High	Low	High
CMR drugs	18 01 01	18 01 08*	18 02 03	18 02 07*
Biological substances	18 01 04	18 01 03*	18 02 03	18 02 02*

* Dangerous or waste needing special supervision.
[1)] Personal protective equipment – 98/686/EEC. [2)] Carcinogenic mutagenic reproductive- toxic.
[3)] Microorganism and infectious agents As in EN 374-1: e.g. bacteria and fungi.

Types

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

Dexterity

Dexterity tested in accordance with DIN EN 420:2003

Performance level	Smallest diameter [1)]
Level 5 (highest level)	5 mm

[1)] Smallest diameter of the pin, to meet the test requirements.

AQL (Acceptable Quality Level)

AQL[1)]= 1,0

[1)] Penetration test (Water leakage test) in accordance with DIN EN 374-2; Requirements of the standard: ≤ 1,5

BERNER INTERNATIONAL GMBH
Mühlenkamp 6
D-25337 Elmshorn
Germany

Fon +49/(0)4121/4356-0
Fax +49/(0)4121/4356-20
info@berner-international.de
www.berner-international.eu

Material	
Polymer-coated Polychloroprene	
Shape	Anatomic fit
Colour	Latte Macchiato (beige)
Powderfree in compliance with TRGS 401/TRGS 540	4
The following allergens are <u>not</u> present:	
Substances	**Measured value [µg/g][1)]**
Latex	n.n.
Protein	n.n.
Thiurame	
Tetramethyl thiuramdisulfide (TMTD)	n.n.
Mercaptobenzothiazole (MBT)	n.n.
Zinc mercaptobenzothiazole (ZMBT)	n.n.
Zinc mercaptobenzimidazole (ZMBI)	n.n.
Dithiocarbamate	
Zinc dibutyldithiocarbamate (ZDBC)	n.n.
Zinc dityldithiocarbamate (ZDEC)	n.n.
Zinc pentamethylenedithiocarbamate (ZPMC)	n.n.
p-Phenylendiamine Derivative	
Diphenylthiourea (DPT)	n.n.
Diphenylguanidine (DPG)	n.n.
Others	
Raloc LC	n.n.
Butylhydroxytoluene (BHT)	n.n.
Butylhydroxyanisole (BHA)	n.n.
[1)] n.d.: Not detectable, i.e. the allergen was not detected or the measured value was below the determined threshold value.	

Material Thickness	
Measuring points	**Material thickness d (measured twice)**
Finger, 15 mm from the end of the tip	≥ 0,40 mm
Middle of the palm of the hand	≥ 0,30 mm
Shaft, 25 mm from the end of the shaft	≥ 0,26 mm

EN 388
0010

Protection against Mechanical Hazards

Mechanical hazards tested in compliance with DIN EN 388:2003. Performance level[1)] coding as follows:

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

[1)] if the value lies below 1 then the result is given as „0“. „X“ means that the test could not be carried out.

EN 374
GLK

Protection against Chemical Hazards

Permeation[1)] is tested for numerous chemicals in compliance with DIN EN 374-3:2003.
Chemical protective gloves (Symbol: Erlenmeyer flask)
Chemical tests according to DIN EN 374-3: GLK= Diethylamine, 96% Sulphuric acid, 40% Sodium hydroxide
Breakthrough times[2)] [min] / performance levels[3)] (1-6) were determined for the following chemicals:

Chemical	Breakthrough time [min]	Performance level
5-Fluorouracil, 10 mg/ml	> 480	6
Carmustine, 3.300 ppm	90	3
Cisplatine, 1.000 ppm	> 480	6
Cyclophosphamide monohydrate, 1000 mg/ 50 ml	> 480	6
Doxorubicin hydrochloride, 2.000 ppm	> 480	6
Etoposide, 20 mg/ml	> 480	6
Ifosfamide, 50 mg/ ml	> 480	6
Methotrexate, 1g/ l	> 480	6
Methotrexate + Ethanol, 1g/l	> 60	3
Vincristine, 1.000 ppm	> 480	6
Sulphuric acid 96%	45	2
Sulphuric acid 40%	> 480	6
Sodium hydroxide 40%	75	3
Sodium hydroxide 10%	> 480	6
Diethylamine	45	2
Acetone	20	1
Acetone nitrile	20	1
Butanone (MEK)	2	0
Ethanol	2	0
Formaldehyde 4%	> 480	6
Glutaraldehyde (1,5-Pentandial) 5%	> 480	6
Hexane	< 7	0
Isopropanol	< 35	2
Methyl methacrylate (MMA)	< 2	0
Methanol	20	1
Xylene	< 2	0

[1)] Movement of a chemical through a material on a molecular level.
[2)] At a permeation rate of 1µg/min·cm². [3)] The performance rate does not reflect the actual duration of protection at the work place!

Protection against Microbiological Hazards

Penetration[1)] requirements met in compliance with EN 374-2:2003. Test results as follows:

Feature	Present?
Tears (visual)	No
Cracks (visual)	No
Holes (visual)	No
Air bubbles (Air leakage test)	No

In accordance with current knowledge, it can be assumed that meeting the penetration requirements provides effective protection against microbiological hazards[2)] (Paragraph 1. DIN EN 374-2 or paragraph 3.2 of DIN EN 374-1).

[1)] Movement of a chemical and/or microorganisms through a porous material on a non-molecular level.
[2)] As in DIN EN 374-1: Bacteria and fungal spores.

Protection against Viruses

Additional Test: Penetration requirements met in accordance with. ASTM F1671[1)].

Test virus	Phi X 174
Test passed	✓

[1)] Additional optional test, as the existing DIN EN 374:2003 Part 1-3 do not contain a virus penetration test:
The bacteriophage Virus Phi X 174 is very small (38 nm (10^{-9})) and therefore especially suitable for this type of test.

Sterilisation

Procedure	Radiation dose D per sterilisation process
Gamma radiation	≥ 25 kGy

CE Mark

CE mark for **complex PPE in category III** in compliance with the **PPE Directive 89/686/EEC.**
The performed **type tests** were based on

- DIN EN 374-1:2003-12
- DIN EN 374-2:2003-12
- DIN EN 374-3:2003-12
- DIN EN 388:2003
- DIN EN 420:2003

Documented by the **EC type test certificate**. **Quality assurance** (EC quality assurance system with monitoring): Inspection measures (usually annually) in compliance with Art. 11B, 89/686/EEC by the intermediary notified body: DGUV Test (0299).

Notified Body „0299“

Technical Committee for Personal Protective Equipment
Testing and Certification Body of DGUV Test,
Zwengenberger Straße 68,
D-42781 Haan, Germany

Additional requirements for medical single use gloves for single use - Notified body, BSI “0086”

DIN EN 455: 2000 - Part 1: Requirements and testing for freedom from holes fulfilled.	✓
DIN EN 455: 2000 - Part 2: Requirements for testing for physical properties fulfilled.	✓
DIN EN 455: 2006 - Part 3: Requirements for biological evaluation fulfilled.	✓

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 compliance with DIN EN ISO 9001:2008. Regular **audits and production site inspections** guarantees the quality of our products.

Storage and Transport Conditions

- Dark (Protect from direct UV light and sunlight
- Cool and dry (+5 to +40°C)
- Protect from carbon dioxide and ozone in high concentrations
- Protect from antiseptic phenols and oil-based derivatives, petroleum, paraffins and lubricants
- No contact with sharp and/or pointed objects

Shelf Life

- 5 years from date of manufacture