Protective Glove Manu Prene XP Product Information

Protective gloves for use with cytostatics and microbiological agents

Summary

- Maximal protection and comfort: Type-tested and certified as complex PPE[1)] of the highest category III; good grip; anatomic shaped, good tactile sensitivity, AQL[2)] = 0.65.
- Area of application: Protective gloves for handling CMR[3)] drugs (e. g. cytostatics and biological agents[4)]).
- Protective properties: Protection against 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

1) Personal protective equipment – PPE Regulation (EU) 2016/425.
2) Acceptable Quality Level
3) Carcinogenic, mutagenic, reproductive-toxic.
4) Microorganism and infectious agents as in EN 374-5: 2016 e.g. bacteria and fungi.

Waste code in accordance to European waste catalogue

	Hazardous potential - Human		Hazardous potential - Animal	
Substance	Low	High	Low	High
CMR-drugs	180101	180108*	180203	180207*
Microorganisms	180104	180103*	180203	180202*

* Dangerous or waste needing special supervision

Versions

Size	XS / 6	S / 6½	SM / 7	M / 7½	ML 8	L / 8½	XL / 9
Order No. (non-sterile – 25 pairs)	2010	2012	2014	2016	2018	2020	2022
Order No. (sterile – 100 Paar)	100234	100235	100236	100237	100238	100239	100240
Length of glove	295 mm						

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

Contact
T +49 4121 4356-0
F +49 4121 4356-20

Web
info@berner-safety.de
www.berner-safety.de

Document ID 297811
Generated F. Holzknecht **Approved** R. Wörl
Valid from 19.02.2025

Flexibility

Dexterity tested in accordance with DIN EN 21420:2020

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

1): Smallest diameter of the pin, to meet the test conditions.

AQL (Acceptable Quality Level)

AQL[1)] = 0,65

1) Penetration test according to EN 374-2:2019; specification according to standard: ≤ 1.5

The following allergens are not present:

Substance		Measured value [µg/g][1)]
Latex		n.d.
Protein		n.d.
Thiurame:	Tetramethyl thiuramdisulfide (TMTD)	n. d.
	Mercaptobenzothiazole (MBT)	n. d.
	Zinc mercaptobenzothiazole (ZMBT)	n. d.
	Zinc mercaptobenzimidazole (ZMBI)	n. d.
Dithiocarbamate:	Zinc dibutyldithiocarbamate (ZDBC)	n. d.
	Zinc detyldithiocarbamate (ZDEC)	n. d.
	Zinc pentamethylenedithiocarbamate (ZPMC)	n. d.
p-Phenylendiamin Derivate:	Diphenylthiourea (DPT)	n. d.
	Diphenylguanidine (DPG)	n. d.
Sonstige:	Butylhydroxytoluene (BHT)	n. d.
	Butylhydroxyanisole (BHA)	n. d.
	Raloc LC	n.d.

1) n.d.: Not detectable, i.e. the allergen was not detected, or the measured value was below the determined threshold value.

Material properties

Material	Polymer-coated Polychloroprene, powder-free
Colour	Latte Macchiato (buff)

Material thickness

Measuring points	Material thickness d (measured double)
Finger, 15 mm from the end of the tip	≥ 0.40 mm
Middle of the palm	≥ 0.30 mm
Shaft, 25 mm from the end of the shaft	≥ 0.26 mm

Protection from chemical hazards

Permeation[1)] was tested to EN ISO 374-1:2016 + A1:2018 / Type A, for numerous chemicals in compliance with EN 16523-1:2015 +A1:2018. Degradation in accordance to EN 374-4:2019. Breakthrough times[2)] [min] / performance levels[3)] (1-6) were determined for the following chemicals:

Chemical	Breakthrough time [min]	Performance class	Degradation
37 % Formaldehyde (T)	> 480	6	-4.1 %
40 % Hydrofluoric acid (S)	> 240	5	-
30 % Hydrogen peroxide (P)	> 480	6	-10.2 %
65 % Nitric acid (M)	> 480	6	-4.6 %
40 % Sodium hydroxide (K)	> 480	6	-18.0 %
96 % Sulphuric acid (L)	> 30	2	8.2 %

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.

Testing in accordance to EN 374-3:2003

Chemical	Breakthrough time [min]	Performance class	Degradation
Acetone	20	1	-
Acetone nitrile	20	1	-
Butanone (MEK)	2	0	-
Carmustine, 3.300 ppm	90	3	-
Cisplatine, 1.000 ppm	> 480	6	-
Cyclophosphamide monohydrate, 1000 mg/ 50 ml	> 480	6	-
Dacarbazine, 10 mg/ ml	75	3	-
Diethylamine	> 30	2	-
Doxorubicin hydrochloride, 2.000 ppm	> 480	6	-
Ethanol	2	0	-
Etoposide, 20 mg/ml	> 480	> 480	-
5-Fluorouracil, 10 mg/ml	> 30	> 30	-
Formaldehyde 4 %	> 480	> 480	-
Glutaraldehyde (1,5-Pentandial) 5 %	> 480	> 480	-
Heptane	20	20	-
Hexane	< 7	< 7	-
Ifosfamide, 50 mg/ml	> 480	> 480	-
Isopropanol, 70 %	< 45	< 45	-
Methanol	20	1	-
Methyl methacrylate (MMA)	< 2	0	-
Mitomycin, 250 mg/ 25 ml*	75	3	-
Mitoxantrone, 2 mg/ ml	75	3	-
Phenol, 5 %	10	1	-
Thiotepa, 10 mg/ml	90	3	-
Toluene	10	2	-

Vincristine, 1.000 ppm	> 480	6	-
Xylene	< 2	0	-

Penetration

Requirements met in compliance with EN 374-2:2019. Water leak test only.

Note: As per clause 4.3 of EN 374-2:2014, the gloves submitted for testing were found to be unsuitable for the air leak test. Therefore as per EN 374-2 only the water leak test has been performed.

Protection against viruses, bacteria & fungi

Requirements met in compliance with EN ISO 374-5:2016. Test results: Pass.

Sterilisation

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

Storage and transport conditions

- Dark (protect from direct UV light and sunlight)
- Cool (+ 5 to + 40° C, optimal + 25° C); dry (relative humidity 30 % - 60 %)
- Protect from carbon dioxide and ozone in high concentrations
- Protect from antiseptic phenols and oil-based derivatives, petroleum, paraffins and lubricants
- No contact with pointed and/or sharp objects

Shelf life

- 5 years from date of manufacture

CE-marking and certifying body

CE marking according to the EU PPE regulation 2016/425 for complex PPE of category III. The performed type tests were based on EN ISO 374-1:2016 + A1:2018 Type A; EN 16523-1:2015 + A1:2018, EN 374-2:2019, EN 374-4:2019; EN 374-5:2016; EN 21420:2020. Documented by EC type test certificate CE 804867.

Notifizierte Stelle ‘’2797’’

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

Manufacturer / Distributor

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