

# PRODUCT INFORMATION

## Protective glove Manu Prene XP

Protective gloves for handling cytotoxic drugs and microbiological agents

### Summary

- + **Maximal protection and comfort:** Type-tested and certified as complex PPE<sup>1)</sup> of the highest category III; good grip; good tactile sensitivity, AQL<sup>2)</sup> = 0.65.
- + **Area of application:** Protective gloves for handling CMR<sup>3)</sup> drugs (e.g. cytostatics and biological agents<sup>4)</sup>).
- + **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

<sup>1)</sup> Personal protective equipment – PPE Regulation (EU) 2016/425. <sup>2)</sup> Acceptable Quality Level <sup>3)</sup> Carcinogenic mutagenic reproductive-toxic.

<sup>4)</sup> Microorganism and infectious agents as in EN 374-5: e.g. bacteria and fungi.

### Versions

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

### Dexterity

Dexterity tested in accordance with EN 420:2003+ A1:2009

Performance level Level 5 (highest level)

Smallest diameter<sup>1)</sup> 5 mm

<sup>1)</sup> Smallest diameter of the pin to meet the test conditions.

### AQL (Acceptable Quality Level)

AQL<sup>1)</sup> = 0.65

<sup>1)</sup> Penetration test according to EN 374-2; specification according to standard: ≤ 1.5.

### The following allergens are not present:

Substances	Measured value [µg/g] <sup>1)</sup>
Latex	n.d.
Protein	n.d.
Thiurame:	Mercaptobenzothiazole (MBT) n.d.
	Tetramethyl thiuramdisulfide (TMTD) n.d.
	Zinc mercaptobenzothiazole (ZMBT) n.d.
	Zinc mercaptobenzimidazole (ZMBI) n.d.
Dithiocarbamate:	Zinc dibutylidithiocarbamate (ZDBC) n.d.

	Zinc dityldithiocarbamate (ZDEC)	n.d.
	Zinc pentamethylenedithiocarbamate	n.d.
<b>p-Phenylendiamin Derivate:</b>	Diphenylguanidine (DPG)	n.d.
	Diphenylthiourea (DPT)	n.d.
<b>Other:</b>	Butylhydroxyanisole (BHA)	n.d.
	Butylhydroxytoluene (BHT)	n.d.
	Raloc LC	

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

## Material

Polymer-coated Polychloroprene, powder-free

Colour	Latte Macchiato (buff)
Shape	Anatomic fit

## Material thickness

Measuring points	Materials thickness d (measured twice)
Finger, 15 mm from the end of the	≥ 0.40 mm
Middle of the palm of the hand	≥ 0.30 mm
Shaft, 25 mm from the end of the	≥ 0.26 mm

## Protection against chemical hazards

**Permeation**<sup>1)</sup> was tested to EN ISO 374-1:2016 / Type B, for numerous chemicals in compliance with EN 16523-1:2015. Breakthrough times<sup>2)</sup> [min] / performance levels<sup>3)</sup> (1-6) were determined for the following chemicals:

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

### Tests according to EN 374-3:2003

Acetone	20	1
Acetone nitrile	20	1
Butanone (MEK)	2	0
Carmustine, 3.300 ppm	90	3
Cisplatin, 1.000 ppm	> 480	6
Cyclophosphamide monohydrate	> 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	6
5-Fluorouracil, 10 mg/ml	> 30	2
Formaldehyde 4%	> 480	6
Glutaraldehyde (1,5-Pentandial) 5%	> 480	6
Heptane	20	1
Hexane	< 7	0
Ifosfamide, 50 mg/ml	> 480	6
Isopropanol, 70%	< 35	2
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
Toluol	10	2
Vincristine, 1.000 ppm	> 480	6
Xylene	< 2	0

<sup>1)</sup> Movement of a chemical through a material on a molecular level. <sup>2)</sup> At a permeation rate of 1µg/min-cm<sup>2</sup>.

<sup>3)</sup> The performance rate does not reflect the actual duration of protection at the work place!

### Degradation according to EN ISO 374-4:2013

30% Hydrogen peroxide (P)	-10.2%
37% Formaldehyde (T)	-4.1%
40% Sodium hydroxide (K)	-18.0%
65% Nitric acid (M)	-4.6%
96% Sulphuric acid (L)	8.2%

### Penetration\*

Requirements met in compliance with EN 374-2:2014. 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.

### Resistance against viruses, bacteria and fungi

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

### Sterilisation

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

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## Storage and Transport Conditions

- + Dark (Protect from direct UV light and sunlight)
  - + Cool and dry (+5 to +40°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
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## Shelf Life

- + 5 years from date of manufacture
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## CE-marking and notified body

**CE mark for complex PPE in category III in compliance with the EU PPE Regulation (EU) 2016/425.**

The performed type tests were based on EN ISO 374-1:2016 Type B; EN 16523-1:2015, EN 374-2:2014, EN 374-4:2013; EN 374-5:2016; EN 420:2003+A1:2009. Documented by EC type test certificate CE 710567.

## Notified body 2797

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## Manufacturer / distributor

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