Protective Glove Manu L Product Information

Latex protective gloves for use with cytostatics and microbiological agents

Summary

- **Maximum protection and comfort:** type tested and certified as complex highest level PPE[1)] (category III); anatomically shaped; extra-long, rolled cuff; good grip; good tactile sensitivity; AQL[2)] =0.65
- **Area of application:** protective gloves for handling CMR[3)] drugs (e.g. cytostatic and virostatic agents) and Microorganisms (like bacteria, virus, etc.)
- **Protection capacity:** protection from all CMR drugs or chemicals is not guaranteed.
- **Glove replacement interval:** In accordance with M 620 of the BGW, the German employers' liability insurance association for health and welfare services: every 30 minutes; after every batch when handling carmustine; immediately in the event of visible contamination. Do not reuse!
- **Protective glove material:** natural latex; latex and carbamates can trigger allergies.
- **Before use:** check for damage. Do not use damaged gloves.
- **Disposal:** waste requiring supervision (waste code: 18 01 04 in accordance with 2000/532/EC); in the event of heavy contamination, waste requiring special supervision (waste code: 18 01 08* in accordance with 2000/532/EC); collect and dispose of waste separately.

1): Personal Protective Equipment – corresponding to the PPE Regulation (EU) 2016/425
2): Acceptable Quality Level
3): Carcinogenic; mutagenic; toxic to reproduction

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	S bzw. 6½	SM bzw. 7	M bzw. 7½	ML bzw. 8	L bzw. 8½	XL bzw. 9
Item-No. (non-sterile, 50 pairs)	4010	4015	4020	4025	4030	4040
Item-No. (sterile, 100 pairs)	100272	100273	100274	100275	100276	100277
Item-No. (sterile, 200 pairs)*				*Phase out	100211	

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Length of gloves	295 mm

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 DIN EN 374-2:2019; specification according to standard: ≤ 1.5, air leakage test passed

The following allergens are not present:

Substance		Measured value [µg/g][1)]
Thiurame:	Tetramethyl thiuramdisulfide (TMTD)	n. d.
	Mercaptobenzothiazole and derivatives	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:	Raloc LC	n. d.
	Butylhydroxytoluene (BHT)	n. d.

	Butylhydroxyanisole (BHA)	n. d.
	Diethylhexylphthalate	n. d.
	Polyvinylchloride (PVC)	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	Natural latex, low in protein / low-allergenic
Colour	Dark blue
Extractable protein content (EN 455-3)	P = < 50 µg/g
Surface treatment	Chlorinated

Powder-free in accordance with TRGS 540

Material thickness

Measuring points	Material thickness d (measured double)
Finger, 15 mm from the end of the tip	≥ 0.96 mm
Middle of the palm	≥ 0.86 mm
Shaft, 25 mm from the end of the shaft	≥ 0.48 mm

Protection from chemical hazards

Permeation[1)] tested for numerous chemicals in accordance with EN 374-1:2016 + A1:2018; test method EN 16523-1:2015 + A1:2018. Degradation in accordance to EN 374-4:2019. Breakthrough times[2)] [min] / performance classes[3)] (1-6) were established for the following chemicals:

Chemical	Breakthrough time [min]	Performance class	Degradation
40 % Sodium Hydroxide (K)	> 480	6	-6.5 %
30 % Hydrogenperoxide (P)	> 480	6	-12.5 %
37 % Formaldehyde (T)	> 480	6	-3.1 %

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.

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Testing in accordance to EN 374-3:2003*

Chemical	Breakthrough time [min]	Performance class	Degradation
Bleomycin, 3 mg/ml	> 180	4	-
Carboplatin, 10 mg/ml	> 90	3	-
Carmustine, 4 mg/ml	60	3	-
Cisplatin, 50 mg/100 ml	105	3	-
Cyclophosphamide Monohydrate, 20 mg/ml	75	3	-
Daunorubicin Hydrochloride, 1,5 g/ml	> 60	3	-
Diethylamine (undiluted)	45	2	-
Doxorubicin Hydrochloride, 1 mg/ml	> 120	4	-
Etoposid, 20 mg/ml	105	3	-
5-Fluorouracil, 1,5 mg/ml	30	2	-
Gemcitabine, 40 mg/ml	95	3	-
Glutaraldehyde, 5 %	> 480	6	-
Isopropanol, 70 %	> 30	2	-
Isopropanol, 70 % + Carmustin , 4 mg/ml	> 120	4	-
Methotrexate 2 mg/ml	> 120	4	-
Mitomycin 1mg/ml	90	3	-
Sulphuric acid 40 %	> 480	6	-
Sulphuric acid 96 %	> 30	2	-
Thiotepa, 10 mg/ml	145	4	-
Vinblastine 1mg/ml	> 180	4	-
Vincristine 1mg/ml	> 120	4	-

Penetration

Tested according to EN 374-2:2019 - test conditions fulfilled. Air leak test only.

Protection against viruses, bacteria & fungi

Tested in accordance to EN ISO 374-5:2016

Sterilisation

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

Storage and transport conditions

- Store in a well-ventilated room, not in a basement
- Dark (protect from direct UV light and sunlight)
- Cool (+ 5 to + 40° C, optimal + 25° C); dry (relative humidity 30 % - 65 %)
- Keep away from equipment or installations that can produce ozone (e.g. through mercury vapour lamps, high voltage equipment, etc.)
- Avoid direct contact with metals, such as copper, magnesium and iron
- Avoid contact with oil-based antiseptic phenols and their derivatives, fats, petrolatum, petroleum, paraffin or other similar compounds
- 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 PSA regulation 2016/425 for complex PPE of category III. Type examination performed based on EN ISO 374-1:2016 + A1:2018 Type B; EN 16523-1:2015 + A1: 2018, EN 374-2:2019, EN 374-4:2019; EN 374-5:2016; EN 21420:2020; EC Type Examination Certificate No. CE 804864;

Notifizierte Stelle ‘’2797’’

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