PRODUCT INFORMATION
PROTECTIVE GLOVE Manu L

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

Versions

Size	S or 6½	SM or 7	M or 7½	ML or 8	L or 8½	XL or 9
Item-No. (non-sterile, 50 pairs)	4010	4015	4020	4025	4030	4040
Item-No. (sterile, 200 pairs)*	100207	100208	100209	100210	100211	100212
Item-No. (sterile, 100 pairs)	100272	100273	100274	100275	100276	100277
***will expire soon**						
Length of gloves	295 mm					

Flexibility

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

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

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

The following allergens are not present:

Substance		Measured value [µg/g][1)]
Thiurame:	Tetramethyl thiuramdisulfide	n.d.
	Mercaptobenzothiazole and	n.d.

	Mercaptobenzothiazole (MBT)	n.d.
	Zinc mercaptobenzothiazole	n.d.
	Zinc mercaptobenzimidazole	n.d.
Dithiocarbamate:	Zinc dibutyldithiocarbamate	n.d.
	Zinc detyldithiocarbamate	n.d.
	Zinc	n.n.
p-Phenylendiamine Derivative:	Diphenylthiourea (DPT)	n.d.
	Diphenylguanidine (DPG)	n.d.
Other:	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

Natural latex, low in protein / low-allergenic

Colour	**Dark blue**
Extractable protein content (EN 455-3)	P = <50 µg/g
Powder-free in accordance with TRGS 540	
Surface treatment	Chlorinated

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; test method EN 16523-1:2015. Degradation in accordance to EN 374-4:2013. Breakthrough times[2] [min] / performance classes[3] (1-6) were established for the following chemicals:

Chemical	**Breakthrough time [min]**	**Performance class**	**Degradation**
37% Formaldehyde (T)	> 480	6	-3.1%
30% Hydrogen peroxide (P)	> 480	6	-12.5%
40% Sodium hydroxide (K)	> 480	6	-6.5%
Testing in accordance to EN 374-3			

Bleomycin 3 mg/ml	> 180	4	-
Carboplatin 10 mg/ml	> 90	3	-
Carmustine 4 mg/ml	60	3	-
Chemical	**Breakthrough time [min]**	**Performance class**	**Degradation**
Cisplatin 50 mg/ml*	105	3	-
Cyclophosphamide *Monohydrate 20 mg/ml	75	3	-
Daunorubicin hydrochloride 1,5 mg/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 % + Carmustine 4 mg/ml	> 120	4	
Methotrexate 2mg/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	

[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.

Penetration

Tested according to EN 374-2:2014- test conditions fulfilled. Air leak test only.

Protection against viruses, bacteria & fungi

Tested in accordance to EN ISO 374-5:2015.

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 Type B; EN 16523-1:2015, EN 374-2:2014, EN 374-4:2013; EN 374-5:2015; EN 420:2003+A1:2009-11; EC Type Examination Certificate No. CE 710563;

Notified body 2797

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