
REV

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)] =1,0
- **Area of application:** protective gloves for handling CMR[3)] drugs (e.g. cytostatic and virostatic agents) and Microorganisms (like bacteria, virus, …)
- **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 89/686/EEC
[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)	4010	4015	4020	4025	4030	4040
Item-No. (sterile)	4011	4016	4021	4026	4031	4041
Length of gloves			295 mm			

Flexibility

Dexterity tested in accordance with DIN EN 420:

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 (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	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

Colour	Dark blue
Low in protein	P = 17 µg/g
Low-allergenic	A < 0,5 µg/g

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	≥ 0,27 mm
Middle of the palm	≥ 0,21 mm
Shaft, 25 mm from the end of the shaft	≥ 0,18 mm

Protection from mechanical hazards

Mechanical hazards tested in accordance with DIN EN 388 (12/03). Performance level[1] coding as follows:

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

[1]: If the value is less than 1, the result should be given as "0". "X" means that the test could not be performed for this kind of product.

Protection from chemical hazards

Permeation[1)] tested for numerous chemicals in accordance with DIN EN 374 Part 3 (12/03). Full protection glove (with symbol: Erlenmeyer flask) - GLK = Diethylamine, 96% sulphuric acid, 40% sodium hydroxide. Breakthrough times[2)] [min] / performance classes[3)] (1-6) were established for the following chemicals:

Chemical	Breakthrough time [min]	Performance class
Bleomycins 3 mg/ml	> 180	4
Carboplatin 10 mg/ml	> 90	3
Carmustine 4 mg/ml	75	3
Isopropanol 70%	> 30	2
Isopropanol 70 % +	> 120	4
Cisplatin 50 mg/ml	> 120	4
Cyclophosphamide Monohydrate	75	3
Doxorubicin hydrochloride 1 mg/ml	> 120	4
Daunorubicin hydrochloride 1,5 mg/ml	> 60	3
5-fluorouracil 1,5 mg/ml	90	3
Methotrexates 2mg/ml	> 120	4
Mitomycin 1mg/ml	90	3
Vinblastines 1mg/ml	> 180	4
Vincristines 1mg/ml	> 120	4
Sulphuric acid 40%	> 480	6
Sulphuric acid 96%	> 30	2
Sodium hydroxide 10%	> 480	6
Sodium hydroxide 30%	> 480	6
Sodium hydroxide 40%	90	3
Glutaraldehyde 5%	> 480	6
Diethylamine (undiluted)	45	2
Hydrogen peroxide 30%	> 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.

Protection from bacteriological hazards

Penetration[1)] requirements met in accordance with DIN EN 374 Part 2 (12/03). Test results as follows:

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

In accordance with current knowledge, it should be assumed that meeting the penetration requirements provides effective protection from microbiological hazards (Paragraph 1 of DIN EN 374, Part 2 and Paragraph 3.2 of EN 374, Part 1).
[1)]: Movement of a chemical and/or microorganism through a porous material on a non-molecular level.

Protection against Viruses

Additional Test: Penetration requirements met in accordance with. ASTM F16711).

Testvirus	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 irradiation	≥ 25 kGy

Storage and transport conditions

Dark (protect from direct UV light and sunlight)

Cool (+5 to +40°C)

Dry

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 the date of manufacture

CE-marking and certifying body

CE mark for complex PPE in category III in accordance with PPE Directive 89/686/EEC
The type test performed was based on DIN EN 374 Parts 1-3, DIN EN 388, DIN EN 420
Documented by EC type test certificate PS 11051010.
Quality assurance (EC quality assurance system with monitoring): Control measures by intermediary notified body DGUV Test (0299) in accordance with Art. 11B, 89/686/EEC.
Certifying body: 0299 DGUV Test - Prüf- und Zertifizierungsstelle Fachbereich Persönliche Schutzausrüstungen, Zwengenberger Strasse 68, D-42781 Haan, Germany

Notified Body BSI „0086“

Additional requirements for medical single use gloves (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	✓
DIN EN 455: 2006 - Part 3: Requirements for biological evaluation fulfilled.	✓

Manufacturer / distributor

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