





PRODUCT INFORMATION PROTECTIVE GLOVE Manu N

Nitrile Protective gloves for use with cytostatics and microbiological agents

Summary

- + **Maximum protection and comfortable to wear:** Type-tested and certified as complex PPE1) of the highest category III; good grip; good tactile sensitivity; ambidextrous.
- + **Area of application:** According to definition of EN 374: Waterproofed gloves with low chemical protection.
- + **Protective properties:** Protective gloves for handling tested substances (» test sheet) and biological agents³⁾. Protection from all CMR pharmaceuticals and chemicals cannot be guaranteed!
- + **Glove replacement interval:** Recommendation for Germany, in accordance with M 620, BGW and DGOP: Change every 30 minutes. In other countries in accordance with the test sheet. Immediately in case of visible contamination. Single use!
- + **Protective glove material:** Nitrile.
- + **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.

Waste code in accordance to European waste catalogue

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

* Dangerous or waste needing special supervision.

¹⁾ Personal protective equipment – 98/686/EEC.

²⁾ Carcinogenic mutagenic reproductive toxic.

³⁾ Microorganism and infectious agents as in EN 374-1: e.g. bacteria and fungi.

Versions

Size	XS or 6	S or 7	M or 8	L or 9	XL or 10
Item No. (non-sterile – 100 pieces)	3010	3015	3020	3025	3030
Item No. (sterile - 50 pairs)	3011	3016	3021	3026	3031
Length of gloves (DIN EN 420)	300 mm				

Per cardboard shipping box: 10 PU - non-sterile; 6 PU - sterile

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 [$\mu\text{g/g}$] ¹⁾
Thiurame:	Tetramethylthiuram disulfide (TMTD)	n.d.
	Mercaptobenzothiazole (MBT)	n.d.
	Zinc mercaptobenzothiazole (ZMBT)	n.d.
	Zinc mercaptobenzimidazole (ZMBI)	n.d.
Dithiocarbamate	Zinc dibutyl dithiocarbamate (ZDBC)	n.d.
	Zinc dibutyl dithiocarbamate (ZDEC)	n.d.
	Zinc pentamethylene dithiocarbamate	n.d.
p-Phenylendiamine	Diphenylthiourea (DPT)	n.d.
	Diphenylguanidine (DPG)	n.d.
Other:	Butylated hydroxytoluene (BHT)	n.d.
	Butylated hydroxyanisole (BHA)	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

Special nitrile mixture

Colour	Light blue Powder-free in accordance with TRGS 540
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Material thickness

Measuring points	Material thickness d (measured double)
Finger, 15 mm from the end of the tip	$\geq 0,27$ mm
Middle of the palm	$\geq 0,21$ mm
Shaft, 25 mm from the end of the shaft	$\geq 0,18$ mm

Protection from mechanical hazards

Mechanical hazards tested in accordance with DIN EN 388 (12/03). Performance level¹⁾ coding as follows:

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

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 bacteriological hazards

Penetration¹⁾ 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 from chemical hazards

Permeation¹⁾ tested for numerous chemicals in accordance with DIN EN 374 Part 3 (12/03). Breakthrough times²⁾ [min] / performance class³⁾ (1-6) were established for the following chemicals:

Chemical	Breakthrough time [min]	Performance class
Ethanol, 35%	> 480 minutes	6
Ethanol, 70%	26 minutes	1
n-Hexane	40 minutes	2
Isopropanol	48 minutes	2
Benzine	45 minutes	2
Suphuric acid, 96%	14 minutes	1
Chlorhexidine (CHX), 4%	> 480 minutes	6
Glutaraldehyde, 1%	> 480 minutes	6
Formaldehyde, 35%	> 480 minutes	6
Perchloric acid 70%	> 480 minutes	6
Ethidium bromide, 1%	> 480 minutes	6
Hydrogen peroxide, 30%	> 480 minutes	6

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 against viruses

Additional penetration test performed in accordance with the American viral protection standard ASTM F1671¹⁾

- also see additional documentation permeation and viral protection 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 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

3 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

Quality assurance (EC quality assurance system with monitoring): Control measures (usually once a year) 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

Manufacturer / distributor

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PERMEATION RESULTS & VIRUS TEST

Nitril protection gloves BERNER Manu N

Protection against chemical hazards

Permeation¹⁾ tested in accordance with the obligatory European standard EN 374 Part 3 (12.03). For the following chemicals the breakthrough times²⁾ [min] / performance categories³⁾ (1-6) were determined:

Tested standard chemicals:	Breakthrough time [min]	Performance class
Hydrogen peroxide, 30%	> 480 minutes	6
Ethanol, 35%	> 480 minutes	1
Ethanol, 70%	26 minutes	0
Methanol	3 minutes	2
n-Hexane	40 minutes	2
Isopropanol	48 minutes	2
Benzine	45 minutes	1
Sulphuric acid, 96%	14 minutes	2
n-Heptane	55 minutes	6
Sodium hydroxide, 40%	> 480 minutes	6
Chlorhexidine (CHX), 4%	> 480 minutes	6
Glutaraldehyde, 1%	> 480 minutes	6
Formaldehyde, 35%	> 480 minutes	6
Perchloric acid, 70%	> 480 minutes	6
Ethidium bromide	> 480 minutes	6

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, as temperature and abrasion may have an effect on these!

Special protection from CMR drugs (cytostatics):

Tested substances:	In accordance with the standard EN 374 Part 3 (12.03)	
Carmustine, 3,3 mg/ml	> 480 minutes	6
Cisplatin, 1 mg/ml	> 480 minutes	6
Cyclophosphamide, 20 mg/ml	> 480 minutes	6
Cytarabine, 100 mg/ml	> 480 minutes	6
Daunorubicin, 5 mg/ml	> 480 minutes	6
Doxorubicin, 2 mg/ml	> 480 minutes	6
Etoposide, 20 mg/ml	> 480 minutes	6
5-Fluorouracil, 50 mg/ml	> 480 minutes	6
Irinotecan hydrochloride, 50 mg/ml	> 480 minutes	6

Methotrexate, 25 mg/ml	> 480 minutes	6
Mitomycin, 0,5 mg/ml	> 480 minutes	6
Oxaliplatine, 5 mg/ml	> 480 minutes	6
Paclitaxel, 6 mg/ml	> 480 minutes	6
Thiotepa, 10 mg/ml	> 480 minutes	6
Vincristine, 1 mg/ml	> 480 minutes	6

Protection against viruses

Additionally tested with the penetration test in accordance with the American virus protection standard ASTM F1671¹⁾

Test virus	Phi X 174
Test passed	4

¹⁾ Additional voluntary test, as the existing EN 374: Parts 1-3 (2003) do not contain a virus test.