PRODUCT INFORMATION
Nitrile Protective Glove Dermagrip Ultra LT

Nitrile protective gloves for use with cytostatics and microbiological agents

Summary

Maximum protection and comfortable to wear: Type-tested and certified as complex PPE[1)] of the highest category III; very good grip due to polymer coating on working side; very smooth on donning side; good tactile sensitivity; ambidextrous; textured surface on fingers and short beaded cuff (glove length 240 mm); AQL[2)]=1,5
Area of application: Protective gloves for handling cytostatics, CMR drugs (e.g. cytostatics, virostatis) and microorganisms & viruses[3)].
Protective properties: Protection from all CMR pharmaceuticals and chemicals cannot be guaranteed!
Glove replacement interval: Recommendation for cytostatics for Germany, in accordance with M 620, BGW and DGOP: Change every 30 minutes. For biological substances after every work cycle. Immediately in case of visible contamination. Single use!
Protective glove material: Nitrile, latex-free.
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.

ersonal protective equipment – 98/686/EEC. [2)] Acceptable quality level (Water test in accordance with QCTM 0053).
arcinogenic mutagenic reproductive toxic

Versions

Size		**S or 6**	**M or 7**	**L or 8**	**XL or 9**
Item No .	**PU= 200 pieces non-sterile**	100176	100177	100178	100179
	PU= Box with 8x50 pieces non-sterile	5011	5016	5021	5026
	Wall mounted for dispenser box	**1 per box**		**3 per box**	
		5050		5051	

Flexibility

Dexterity tested in accordance with EN 420+A1:2009

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

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

Material

100 % Nitrile (Acrylonitrile butadiene)	
Colour	blue, powder-free in accordance with TRGS 540

Material thickness

Measuring points	**Material thickness (measured twice)**
Finger, 15 mm from the end of the tip	≥ 0,07 mm
Middle of the palm	≥ 0,06 mm
Shaft, 25 mm from the end shaft	≥ 0,05 mm

The following allergens are not present

Substances		Messwert [µg/g][1)]
Thiurame:	Tetramethyl thiuramdisulfide (TMTD)	n.n.
	Mercaptobenzothiazol (MBT)	n.n.
	Zinkmercaptobenzothiazol (ZMBT)	n.n.
	Zinkmercaptobenzimidazol (ZMBI)	n.n.
Dithiocarbamate:	Zinkdibutyldithiocarbamate (ZDBC)	n.n.
	Zinkdityldithiocarbamate (ZDEC)	n.n.
	Zinkpentamethylenedithiocarbamate	n.n.
	Zinc dimethyldithiocarbamate (ZDMC)	n.n.
p-Phenylendiamin Derivate:	Diphenylthiourea (DPT)	n.n.
	Diphenylguanidine (DPG)	n.n.
Other:	Butylhydroxytoluene (BHT)	n.n.
	Butylhydroxyanisol (BHA)	n.n.

[1] n.d.: Not detectable, i.e. the allergen was not detected or the measured value was below the determind threshhold value.

Protection against chemical hazards

Permeation[1)] tested for numerous chemicals in accordance with EN 16523-1:2015. (* Tests in accordance to EN 374-3:2003). Degradation in accordance to EN 374-4:2013. Breakthrough times[2)] [min] / performance classes[3)] (1-6) were established for the following chemicals:

Chemicals	Breakthrough time [min]	Performance level
n-Heptane (J)	17	1
Sodiumhydroxide, 40% (K)	> 480	6
Formaldehyde, 37% (T)	241	5
Hydrogen peroxide, 30% (P)	241	5
***Test in accordance to EN 374-3:2003**		
Carboplatin 10 mg/ml	> 120	4
Carmustin 100 mg/ 25 ml	> 60	3
Cisplatin 50 mg/ 100 ml	> 120	4
Cyclophosphamide Monohydrate 500 mg/ 25 ml	> 60	3
5-Fluorouracil 1,5 mg/ml	> 120	4
Sulphuric acid 96%	> 30	2
Sodium hydroxide 40%	> 60	3
Isopropanol 70%	> 30	2
Glutaraldehyde 5%	> 60	3
Diethylamin (unverdünnt)	> 30	2
Daunorubicin 150 mg/ ml	> 120	4
Doxorubicin chlorhydrate 1mg/ ml	> 60	3
Etoposide 20 mg/ml	> 60	3

Paclitaxel 6 mg/ 50 ml	> 60	3
Thiotepa	> 60	3
Dacarbazine 10 mg/ ml	> 60	3
Ifosfamide 50 mg/ ml	> 30	2
Mitoxantron 2mg / ml	> 120	4
Vincristin 1 mg/ ml	> 120	4
Mitomycin 250 mg / 25 ml	> 30	2

[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, because they may be affected by temperature and abrasion!

Penetration

Penetration[1] tested in accordance to EN 374-2:2014. Test passed.

Resistance against viruses, bacteria and fungi

Requirements met in accordance to 374-5:2016.

Additional requirements for medical gloves

In accordance to 93/42/EEC (CE class 1): EN 455:2000 – Parts 1, 2 ,3 ,4

Additional test in accordance to ASTM D 6319

Standard Specification for Nitrile Examination Gloves for Medical Applications

Quality management

Our **quality management system** is **tested and certified** by TÜV Management Service GmbH in compliance with DIN EN ISO 9001:2015. Regular **audits and production site inspections** guarantees the quality of our products.

Storage and transport conditions

Dark (protect from direct UV light and sunlight);
Cool (+5 to +40°C) , dry;
No contact with pointed or sharp objects

Shelf life

5 years from date of manufacture

CE-Marking and notified body

CE-marking in accordance to PPE regulation EU 2016/425 for complex PPE in category III, tested to EN 420:2003+A1:2009, EN ISO 374-1:2016 Type B, EN ISO 374-5:2016. Documented as **EU type test certificate CE 688314**. The EU-declaration of conformance is available at: www.berner-safety.de.
Notified body: BSI, Kitemark Court, Davy Avenue, Milton Keynes, MK5 8PP, Great Britain.

Manufacturer

WRP Asia Pacific SDN BHD, Lot 1, Jalan 3; Kawasan Perusahaan, Bandar Baru Salak Tinggi; Sepang, Selangor Darul Ehsan, Selang 43900; Malaysia

Distributor

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