Protective gloves for chemicals, cytostatics and biological agents

Application range and properties

- **Maximum protection and comfortable to wear:** Type-tested and certificated as complex PPE[1)] of the highest category III in accordance to EN 420 and as surgical gloves to EN 455; powder free; good grip; anatomical shape, textured; AQL[2)] = 1,5 (Water test)
- **Application range:** Protection against chemical dangers, CMR-medical drugs, biological agents and viruses.
- **Protective properties:** For handling the substances listed (see permeation table) and biological agents. 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. In other countries in accordance with the test sheet. For biological substances after every work cycle. Immediately in case of visible contamination. Single use!
- **Protective glove material:** Latex, low-allergenic, protein content 12 µg/dm².
- **Before use:** Check for damage! Do not use damaged gloves!
- **Disposal:** Waste in need of supervision or need of special supervision, e.g.:
  European waste code (EWC) for cytostatic highly contaminated waste: 18 01 08* as per 2000/532/EC
  Waste code for infective agents highly contaminated waste: 18 01 03* as per 2000/532/EC

[1)]: Personal Protective Equipment as per 89/6896/EEC
[2)]: Acceptable Quality Level
[3)]: Cancerogenic mutagenic reproductive toxic

Versions

Size		**XS or 6**	**S or 6½**	**SM or 7**	**M or 7½**	**ML or 8**	**L or 8½**	**XL or 9**
Order No.	**Non-sterile**	100007	100008	100009	100010	100011	100012	100013

Packaging: Dispenser box with 25 pairs; PU = 6 pairs per outer packaging

Flexibility

Dexterity tested in accordance to EN 420:

Performance level	**Smallest diamter [1)]**
Level 5 (highest level)	5 mm

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

Material

Natural rubber (Latex)

Low in protein to EN 455-3	P = 12 µg/g
Low in allergens	A < 0,3 µg/g
Powder-free in accordance to ASTM D 6124	yes
Colour	Vanilla
Shape	Anatomical
Material strength: Measuring points	**Material strength d (measured twice)**
Finger, 15 mm from the end of the tip	≥ 0,52 mm
Hand inner surface in the middle	≥ 0,44 mm
Shaft, 25 mm from the end shaft	≥ 0,34 mm
Glove length to EN 420	290 mm

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The following allergens are not present:	
Substance	**Measured value [µg/g][1)]**
Thiurame	
Tetramethyl thiuramdisulfide (TMTD)	n.d.
Mercaptobenzothiazol (MBT)	n.d.
Zinkmercaptobenzothiazol (ZMBT)	n.d.
Zinkmercaptobenzimidazol (ZMBI)	n.d.
Dithiocarbamate	
Zinkdibutyldithiocarbamate (ZDBC)	n.d.
Zinkdityldithiocarbamate (ZDEC)	n.d.
Zinkpentamethylenedithiocarbamate (ZPMC)	n.d.
p-Phenylendiamin Derivate	
Diphenylthiourea (DPT)	n.d.
Diphenylguanidine (DPG)	n.d.
Other	
Butylhydroxytoluene (BHT)	n.d.
Butylhydroxyanisol (BHA)	n.d.

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

Protection from mechanical hazards

Mechanical hazards tested in accordance with EN 388 (12/03). Performance level[1)] 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

Penetration[1)] requirements met in accordance with 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 374, Part 2 and Paragraph 3.2 of EN 374, Part 1).

[1)]: Movement of a chemical and/or micro-organisms through porous material on a non-molecular level.

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
Cyclophosphamide Monohydrate 20 mg/ml	65 min	3
5-Fluorouracil 1,5 mg/ml	90 min	3
Methotrexate 2 mg/ml	65 min	3
Sulphuric acid 96%	> 30 min	2
Natriumhydroxide 40%	> 60 min	3
Diethylamine (undiluted)	> 30 min	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!

Protection against viruses

Additional test: Penetration test in accordance to ASTM F1671[1)] – Test passed.

Test virus Phi X 174	✓

[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..

Notified body BSI „0086“

Additional requirements for medical gloves for single use
in accordance of the EU directive 93/42/EEC (CE class IIa).

DIN EN 455:2000 – Part 1: Requirements and testing for freedom of holes	✓
DIN EN 455:2000 – Part 2: Requirements and testing for physical properties	✓
DIN EN 455:2000 – Part 3: Requirements and testing for biological evaluation	✓

CE-Marking

CE-marking in accordance to **PPE-directive 89/686/EEC** for **complex PPE of category III**.
Type-test No. CE579719 based on

- DIN 374 Parts 1-3, EN 388, EN 420

Additionally tested as surgical gloves to EN 455 parts 1-3 in accordance with the directive 93/42/EEC (CE classKlasse IIa).

Qualitätssicherung (EG-Qualitätssicherungssystem mit Überwachung): Kontrollmaßnahmen (jährlich) gem. Art. 11B, 89/686/EWG durch die notifizierte Stelle BSI (0086). Qualitätsmanagement beim Hersteller entsprechend EN ISO 9001, EN ISO 13485 und FDA Quality System Regulation (QRS).

Notified body „0086“

BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP, UK.

Quality management system

Our **quality management system** is **tested and certified** by TÜV Management Service GmbH (a certification body accredited by the German Accreditation Council) in compliance with DIN EN ISO 9001:2008. 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
- 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

- 3 years from the date of manufacture

Manufacturer

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

Distributor

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