



Neoprene-Protective-Gloves



Area of Application and Features

- **Maximal protection and comfort:** Type-tested and certified as complex PPE<sup>1)</sup> of the category III; good grip; good tactile sensitivity.
- **Area of application:** Protective gloves for handling CMR<sup>2)</sup> drugs (e.g. cytostatics) and biological agents<sup>3)</sup>.
- **Protective properties:** Protection from all CMR pharmaceuticals cannot be guaranteed!
- **Glove replacement interval:** Change every 30 minutes (in accordance with M 620, BGW – German Employer's Liability Association for Health and Welfare); after every manufacturing batch when handling Carmustine or Thiotepa; immediately in case of visible contamination. Only suitable for single use!
- **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:

| Substance             | Origin              |           |          |           |
|-----------------------|---------------------|-----------|----------|-----------|
|                       | Human               |           | Animal   |           |
|                       | Hazardous potential |           |          |           |
|                       | Low                 | High      | Low      | High      |
| CMR drugs             | 18 01 01            | 18 01 08* | 18 02 03 | 18 02 07* |
| Biological substances | 18 01 04            | 18 01 03* | 18 02 03 | 18 02 02* |

\* Dangerous or waste needing special supervision.

<sup>1)</sup> Personal protective equipment.

<sup>2)</sup> Cancerogenic mutagenic reproductive toxic.

<sup>3)</sup> Microorganism and infectious agents As in EN 374-1: e.g. bacteria and fungi.

Types

| Size                      | XS or 6     | S or 6½ | SM or 7 | M or 7½ | ML or 8 | L or 8½ | XL or 9 |      |
|---------------------------|-------------|---------|---------|---------|---------|---------|---------|------|
| Item no.<br>PU = 25 Pairs | Non-sterile | 2010    | 2012    | 2014    | 2016    | 2018    | 2020    | 2022 |
|                           | Sterile     | 2011    | 2013    | 2015    | 2017    | 2019    | 2021    | 2023 |

Dexterity

Dexterity tested in accordance with DIN EN 420:2003

| Performance level | Smallest diameter <sup>1)</sup> |
|-------------------|---------------------------------|
| Level 5           | 5 mm                            |

<sup>1)</sup> Smallest diameter of the pin, to meet the test requirements.

AQL (Acceptable Quality Level)

AQL<sup>1)</sup> = 1,0

<sup>1)</sup> Penetration test (Water leakage test) in accordance with DIN EN 374-2; Requirements of the standard: ≤ 1,5



| <b>Material</b>  |   |
|--|---|
| <b>Polymer-coated Polychloroprene</b>  |   |
| Shape  | Anatomic fit  |
| Colour   | beige   |
| Powder-free in compliance with TRGS 540  | ✓   |
| <b>The following allergens are not present:</b>  |   |
| <b>Substances</b>  | <b>Measured value [<math>\mu\text{g/g}</math>]<sup>1)</sup></b> |
| Latex  | n.n.  |
| Protein  | n.n.  |
| <b>Thiurame</b>  |   |
| Tetramethyl thiuramdisulfide (TMTD)  | n.n.  |
| Mercaptobenzothiazole (MBT)  | n.n.  |
| Zinc mercaptobenzothiazole (ZMBT)  | n.n.  |
| Zinc mercaptobenzimidazole (ZMBI)  | n.n.  |
| <b>Dithiocarbamate</b>   |   |
| Zinc dibutyldithiocarbamate (ZDBC)   | n.n.  |
| Zinc dityldithiocarbamate (ZDEC)   | n.n.  |
| Zinc pentamethylenedithiocarbamate (ZPMC)  | n.n.  |
| <b>p-Phenylendiamine Derivative</b>  |   |
| Diphenylthiourea (DPT)   | n.n.  |
| Diphenylguanidine (DPG)  | n.n.  |
| <b>Others</b>  |   |
| Raloc LC   | n.n.  |
| Butylhydroxytoluene (BHT)  | n.n.  |
| Butylhydroxyanisole (BHA)  | n.n.  |
| <sup>1)</sup> n.d.: Not detectable, i.e. the allergen was not detected or the measured value was below the determined threshold value. |   |
| <b>Material Thickness</b>  |   |
| <b>Measuring points</b>  | <b>Material thickness d (measured twice)</b>                    |
| Finger, 15 mm from the end of the tip  | ≥ 0,40 mm   |
| Middle of the palm of the hand   | ≥ 0,30 mm   |
| Shaft, 25 mm from the end of the shaft   | ≥ 0,26 mm   |



### Protection against Mechanical Hazards

**Mechanical hazards** tested in compliance with DIN EN 388:2003. Performance level<sup>1)</sup> coding as follows:

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

<sup>1)</sup> If the value is less than 1, the result is recorded as "0". "X" means that the test could not be performed.



### Protection against Chemical Hazards

**Permeation**<sup>1)</sup> is tested for numerous chemicals in compliance with DIN EN 374-3:2003. Breakthrough times<sup>2)</sup> [min] / performance levels<sup>3)</sup> (1-6) were determined for the following chemicals:

| Chemical                     | Breakthrough time [min] | Performance level |
|------------------------------|-------------------------|-------------------|
| Carmustine                   | 90                      | 3                 |
| Cisplatin                    | > 480                   | 6                 |
| Cyclophosphamide monohydrate | > 480                   | 6                 |
| Doxorubicin hydrochloride    | > 480                   | 6                 |
| Vincristine                  | > 180                   | 4                 |
| 96% Sulphuric acid           | 45                      | 2                 |
| 40% Sodium hydroxide         | 75                      | 3                 |
| Diethylamine                 | 45                      | 2                 |

<sup>1)</sup> Movement of a chemical through a material on a molecular level.

<sup>2)</sup> At a permeation rate of 1µg/min·cm<sup>2</sup>.

<sup>3)</sup> The performance rate does not reflect the actual duration of protection at the work place!



### Protection against Microbiological Hazards






**Penetration**<sup>1)</sup> requirements met in compliance with EN 374-2:2003. Test results as follows:

| Feature                        | Present? |
|--------------------------------|----------|
| Tears (visual)                 | No       |
| Cracks (visual)                | No       |
| Holes (visual)                 | No       |
| Air bubbles (Air leakage test) | No       |

In accordance with current knowledge, it can be assumed that meeting the penetration requirements provides effective protection against microbiological hazards<sup>2)</sup> (Paragraph 1. DIN EN 374-2 or paragraph 3.2 of DIN EN 374-1).

<sup>1)</sup> Movement of a chemical and/or microorganisms through a porous material on a non-molecular level.

<sup>2)</sup> As in DIN EN 374-1: Bacteria and fungal spores.

|  |   |
|--|---|
|  <b>Protection against Viruses</b>  |   |
| <b>Additional Test: Penetration</b> requirements met in accordance with. ASTM F1671-97b <sup>1)</sup> .  |   |
| Test virus   | Phi X 174   |
| Test passed  | ✓   |
| <sup>1)</sup> Additional optional test, as the existing DIN EN 374:2003 Part 1-3 do not contain a virus penetration test:<br>The bacteriophage Virus Phi X 174 is very small (38 nm (10 <sup>-9</sup> )) and therefore especially suitable for this type of test.  |   |
|  <b>Sterilisation</b>   |   |
| <b>Procedure</b>   | <b>Radiation dose D per sterilisation process</b> |
| Gamma radiation  | ≥ 25 kGy  |
|  <b>CE Mark</b>   |   |
| CE mark for <b>complex PPE in category III</b> in compliance with the <b>PPE Directive 89/686/EEC</b> .<br>The performed <b>type tests</b> were based on <ul style="list-style-type: none"> <li>▪ DIN EN 374-1:2003-12</li> <li>▪ DIN EN 374-2:2003-12</li> <li>▪ DIN EN 374-3:2003-12</li> <li>▪ DIN EN 388:2003</li> <li>▪ DIN EN 420:2003</li> </ul> Documented by the <b>EC type test certificate</b> No. PS 09050018.<br><b>Quality assurance</b> (EC quality assurance system with monitoring):<br>Inspection measures (usually annually) in compliance with Art. 11B, 89/686/EEC by the intermediary notified body: BG-PRÜFZERT (0299). |   |
|  <b>Notified Body „0299“</b>  |   |
| Technical Committee for Personal Protective Equipment<br>Testing and Certification Body of BG-PRÜFZERT<br>Centre for Safety Technology<br>Zwengenberger Strasse 68<br>D-42781 Haan<br>Germany  |   |
|  <b>Quality Management System</b>   |   |
| Our <b>quality management system</b> is <b>tested and certified</b> by TÜV Management Service GmbH (a certification body accredited by the German Accreditation Council) in compliance with DIN EN ISO 9001:2000. Regular <b>audits and production site inspections</b> guarantees the quality of our products.  |   |



**Storage and Transport Conditions**

- Dark (Protect from direct UV light and sunlight)
- Cool and dry (+5 to +40°C)
- Protect from carbon dioxide and ozone in high concentrations
- Protect from antiseptic phenols and oil-based derivatives, petroleum, paraffins and lubricants
- No contact with sharp and/or pointed objects



**Shelf Life**

- 3 years from date of manufacture