



| | | |
|----------------------|-------------------------------------|---|
| Product: | GentleSafe® EXTRA |  |
| Trademark: | SAFE® | |
| REF: | 884 | |
| Manufacturer: | DACH Schutzbekleidung GmbH & Co. KG | |




| | |
|----------------------------------|---|
| Classification: | CAT III according to Regulation (EU) 2016/425 for personal protective equipment (PPE). Class I according to Regulation (EU) 2017/745 for medical devices; UMDNS code: 11-882. |
| Materials: | Carboxylated nitrile butadiene rubber |
| Product description: | <p>The extra long nitrile glove is liquid impermeable, powder-free and free of natural latex. It offers excellent dexterity with high comfort (dexterity level 5/5). High elasticity with low effort. No hand fatigue.</p> <p>Ambidextrous wearable, with rolled edge, non-sterile, excellent tactile sensation. Textured surface on the fingertips. Excellent grip, even when handling wet or moist objects. Excellent performance against chemicals and tested against cytostatics, viruses, bacteria and fungi. Also suitable for food contact. Extra long shaft for even more safety.</p> |
| Pictograms and standards: |  |

| | | | |
|-----------------------------|--|-------|---------------------------------|
| Product performance: | <i>Testing against chemicals</i> | | |
| | EN ISO 374-1:2016+A1:2018 and EN 16523-1:2015+A1:2018 | | |
| | Chemical | Level | EN ISO 374-4:2019 Degradation % |
| | 40% Sodium Hydroxide (K) | 6 | 14.9 |
| | 30% Hydrogen Peroxide (P) | 3 | 31.6 |
| | 37% Formaldehyde (T) | 4 | 13.0 |
| | <i>Other tested Chemicals:</i> | | |

| | | | |
|--|---|--|---|
| | 1,5% Methanol in water (CAS: 67-56-1) | 6 | 14.5 |
| | 10% Acetic acid (CAS: 64-19-7) | 5 | 16.5 |
| | 50% Sulphuric acid (CAS: 7664-93-9) | 6 | -23.4 |
| | 4% Chlorhexidine digluconate (CAS: 18472-51-0) | 6 | 22.1 |
| | 3% Povidone iodine (CAS: 25655-41-8) | 5 | 26.7 |
| | 10%-13% Sodium hypochlorite (14% active chlorine) (CAS: 7681-52-9) | 6 | 23.9 |
| | 10% Sodium Percarbonate | 5 | 25.6 |
| | 50% Glutaraldehyde (CAS: 111-30-8) | 6 | -10.1 |
| | 5% Ethidium bromide (CAS: 1239-45-8) | 6 | -5.2 |
| | 0,1% Phenol (CAS: 108-95-2) | 6 | -2.6 |
| | Testing against infective agents accordingly EN ISO 374-5:2016 and ISO 16604:2004 | | |
| | Protection against bacteria and fungi | Pass | |
| | Protection against viruses | Pass | |
| | Determination of resistance to penetration accordingly EN 374-2:2014 | | |
| | Air leak test | Pass | |
| | Water leak test | Pass | |
| | Testing against the permeation of cytostatic drugs | | |
| | ASTM D6978-05(2019) | | |
| | Chemical | Minimum breakthrough detection time (Specimen 1/2/3) (Minutes) | Average steady state permeation rate (Specimen 1/2/3) (µg/cm²/Minute) |

| | | | |
|--|---|--------------------------|---------------------|
| | Carmustine (BCNU), 3.3 mg/ml (3,300 ppm) | 14.7 (15.1, 14.7, 16.8) | 0.6 (0.5, 0.5, 0.7) |
| | Cisplatin, 1 mg/ml (1,000 ppm) | >240 | N/A |
| | Cylophosphamid (Cytoxan) 20.0 mg/ml (20,000 ppm) | >240 | N/A |
| | Dacarbazine 10.0 mg/ml (10,000 ppm) | >240 | N/A |
| | Doxorubicin HCl 2 mg/ml (2,000 ppm) | >240 | N/A |
| | Etoposide 20.0 mg/ml (20,000 ppm) | >240 | N/A |
| | Fluorouracil 50.0 mg/ml (50,000 ppm) | >240 | N/A |
| | Ifosfamide 50.0 mg/ml (50,000 ppm) | >240 | N/A |
| | Methotrexate 25 mg/ml (25,000 ppm) | >240 | N/A |
| | Mitomycin C 0.5 mg/ml (500 ppm) | >240 | N/A |
| | Mitoxantrone 2.0 mg/ml (2,000 ppm) | >240 | N/A |
| | Paclitaxel 6.0 mg/ml (6,000 ppm) | >240 | N/A |
| | ThioTepa 10.0 mg/ml (10,000 ppm) | 58.8 (110.0, 58.8, 67.0) | 0.5 (0.3, 0.5, 0.6) |
| | Vincristine Sulfate 1.0 mg/ml (1,000 ppm) | >240 | N/A |
| | Dexterity and innocousness of material testing | | |
| EN ISO 21240:2020 | | | |
| Dexterity | | Level 5 | |
| pH Level | | Pass | |
| Polycyclic Aromatic Hydrocarbons Content | | Not detected - Pass | |

| | | | |
|-------------------|---|---|---------|
| | <i>Food safety testing</i> | | |
| | Resolution ResAP (2004) 4 and Regulation (EG)1935/2004 | | |
| | Overall migration | | Pass |
| | Specific migration of primary aromatic amine | | Pass |
| | Specific migration of nitrosamine and nitrosatable substances | | Pass |
| | <i>Medical examination gloves testing</i> | | |
| | Standard | Test | Result |
| | EN 455-1:2000 | Freedom from holes | Pass |
| | EN 455-2:2015 | Physical properties: | Pass |
| | Partial tests | Length: 300±10 mm | 291 mm |
| | | Width S: 85±5 mm | 84 mm |
| | | Width M: 95±5 mm | 93 mm |
| | | Width L: 105±5 mm | 104 mm |
| | | Width XL: 115 mm±5 mm | 113 mm |
| | | Force at break: ≥ 6.0 N | ≥ 6.0 N |
| | | Force at break after challenge testing: ≥ 6.0 N | ≥ 6.0 N |
| | EN 455-3:2015 | Labelling | Pass |
| | Partial tests | Gloves shall not be dressed with talcum powder (magnesium silicate) | Pass |
| | | Powder residues < 2mg | 0,5 mg |
| | EN 455-4 | Shelf life | Pass |
| Thickness: | Cuff: 0,08 mm; Palm: 0,11 mm; Finger: 0,15 mm (± 0,02 mm) | | |
| Weight: | S: 6,0g, M: 6,5g, L: 6,9g, XL: 7,3g (± 0,3g) | | |

| | |
|----------------------------|--|
| Physical properties | <p>Tensile strength before ageing: ≥ 15 MPa</p> <p>Tensile strength after ageing: ≥ 14 MPa</p> <p>Elongation before ageing: $\geq 500\%$</p> <p>Elongation after ageing: $\geq 400\%$</p> |
| Other features: | <p> No intolerance reactions: This product does not contain natural latex.</p> <p> Virus-tight according to ASTM 1671: Determination of the resistance of materials to the penetration of viral pathogens.</p> <p> Non sterile.</p> |
| Color: | Blue |

| Packaging and variants: | Packaging | Quantity |
|--------------------------------|--|-----------------|
| | Dispenser box | 100 Stk. |
| | Shipping Carton | 1000 Stk. |
| GTIN: | 884/B/S | 4049825007739 |
| | 884/B/M | 4049825007746 |
| | 884/B/L | 4049825007753 |
| | 884/B/XL | 4049825007760 |
| Limitation: | <p>The gloves are designed for single use.</p> <p>The duration of protection in working use may differ from the breakthrough time determined according to EN 374, as it depends on the working conditions.</p> | |
| Storage: | <p>Store in a dry place without direct sunlight in the original packaging (see packaging).</p> <p>If the storage conditions are observed, the product has a storage life of 5 years (see labeling on the product).</p> | |



| | |
|---|--|
| Environmental sustainability and disposal: | <p>In the case of contaminated products, the type and extent of contamination determines the disposal, and the applicable laws and regulations of the relevant country must be followed.</p> <p>A non-contaminated product can be thermally recycled or disposed of in landfills without releasing toxic substances.</p> <p>The recyclable packaging (dispenser box and shipping carton) is made of cardboard.</p> |
|---|--|