



Nitril-Handschuhe CELOS Glove 2.30

pure¹¹-Nr.: 1130311 Hersteller: pure¹¹

Zusammenfassung

- Steril
- Material: Nitril
- Handspezifisch
- Gut geeignet zum Double Gloving
- AQL-Wert (Acceptable Quality Level): 0,65
- Volltexturierung und sehr guter Grip
- Vulkanisationsbeschleunigerfrei
- Exzellentes Fingerspitzengefühl
- Verringertes Allergierisiko
- Gegen eine Vielzahl von Zytostatika geprüft
- Niedrige Partikelwerte
- Nachgereinigt mit 0,2 µm gefiltertem DI-Wasser
- 4-fache Verpackung mit Recyclinganteil

Empfohlene Reinraumklassen

ISO 3 4 5 6 7 8 9

GMP A/B C D

pure¹¹-Nr.: 1130311BL6

Farbe: Blau / Größe: 6,0 / VE: 200 Paar

pure¹¹-Nr.: 1130311BL6_5

Farbe: Blau / Größe: 6,5 / VE: 200 Paar

pure¹¹-Nr.: 1130311BL7

Farbe: Blau / Größe: 7,0 / VE: 200 Paar

pure¹¹-Nr.: 1130311BL7_5

Farbe: Blau / Größe: 7,5 / VE: 200 Paar

pure¹¹-Nr.: 1130311BL8

Farbe: Blau / Größe: 8,0 / VE: 200 Paar

pure¹¹-Nr.: 1130311BL8_5

Farbe: Blau / Größe: 8,5 / VE: 200 Paar

pure¹¹-Nr.: 1130311BL9

Farbe: Blau / Größe: 9,0 / VE: 200 Paar

pure¹¹-Nr.: 1130311BL10

Farbe: Blau / Größe: 10,0 / VE: 200 Paar

CELOS® Glove Nitrile 2.30

Product information:

<i>Material</i>	100% pure Nitrile
<i>Design</i>	Beaded cuff and micro-textured throughout the glove
<i>Application</i>	Sterile cleanroom glove for highest requirements, for industrial use only
<i>Color</i>	Dark blue
<i>Cuff Thickness</i>	0.09 mm (+/- 0.01 mm)
<i>Palm Thickness</i>	0.11 mm (+/- 0.01 mm)
<i>Thickness at Finger</i>	0.13 mm (+/- 0.01 mm)
<i>Length</i>	Min. 310 mm
<i>AQL</i>	0.65

Products:

<i>Part number</i>	<i>Style</i>	<i>Variant</i>	<i>Inner packing</i>	<i>Quantity per case</i>
1130311	Sterile	1130311BL6	1 pair/1 peel pouch	4 intermediate bags/LDPE carton liner and case
		1130311BL6_5	10 peel pouches/1 outer bag	
		1130311BL7	5 outer bags/1 intermediate bag	200 pairs/case
		1130311BL7_5		
		1130311BL8		
		1130311BL8_5		
		1130311BL9		
		1130311BL10		

Characteristics:

- Glove of newest generation
- Hand specific
- Tacky with micro-texture throughout the glove
- Without accelerator - reduced allergy risk
- Without plasticizers, phthalates, silicone oil and amide
- No sulphur added during compounding process
- Cleanroom produced and packed
- 40% recycled materials for inner bag, outer bag, intermediate bag and carton liner
- 90% recycled materials for carton box

pure¹¹ has made every attempt to ensure the accuracy and reliability of the information provided in this datasheet. However, the information is provided "as is" without warranty of any kind. pure¹¹ does not accept any responsibility or liability for the accuracy, content, completeness, legality, or reliability of the information contained.



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Performance parameter:

		Specification	Unit
Fluoride	F ⁻	< 0.010	µg/cm ²
Chloride	Cl ⁻	< 0.300	µg/cm ²
Nitrite	NO ₂ ⁻	< 0.010	µg/cm ²
Bromide	Br ⁻	< 0.010	µg/cm ²
Nitrate	NO ₃ ⁻	< 0.200	µg/cm ²
Phosphate	PO ₄ ³⁻	< 0.010	µg/cm ²
Sulphate	SO ₄ ²⁻	< 0.050	µg/cm ²
Sodium	Na ⁺	< 0.050	µg/cm ²
Calcium	Ca ²⁺	< 0.300	µg/cm ²
Magnesium	Mg ²⁺	< 0.010	µg/cm ²
Potassium	K ⁺	< 0.050	µg/cm ²
Zinc	Zn ²⁺	< 0.080	µg/cm ²
Ammonium	NH ₄ ⁺	< 0.050	µg/cm ²

Physical and Chemical Properties:

	Specification	Unit
Force at Break (after aging)	≥ 6	N
Tensile Strength	≥ 14	MPa
Elongation	≥ 400	%
LPC ≥ 0.5 µm	< 1000	Counts/cm ²
NVR (DI water)	< 3.00	µg/cm ²
Silicone Oil, Amide and DOP-FTIR	Not detected	
Endotoxin	< 10	Units/glove

Additional important Product information:

According to the EN 21420 : 2020 test, it is confirmed that during the production of CELOS gloves 1130311, none of the following chemicals are introduced into the production process, thus reducing allergic reactions

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| <ul style="list-style-type: none"> • Thiram disulfide • Dithiocarbamates • Mercaptobenzothiazole / MBT derivatives • 1,3 - diphenylguanidine • Duphenylthiourea, dibutylthiourea • Formaldehyde • Bisphenol A | <ul style="list-style-type: none"> • Bezoisothiazolinine • Cethylpyridinium Chloride • Triphenyl phosphite, triphenyl phosphate, tricesyl phosphate • Abietic acid derivatives • Nickel |
|--|--|

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Parameter	Test method	Result
Chemotherapy Test	EN455 Part 1:2020 EN455 Part 2:2015 EN455 Part 3:2015	Pass
Water-Leak-Test	EN ISO 374-2:2019	Pass
Permeation	ASTM D6978-05(2019)	See table below
Degradation	EN ISO 374-4:2019 EN ISO 374-1:2016+A1:2018	See table below
Microbiological Testing	ISO 10993-5	See table below
Gamma Irradiation	ISO 13485	See table below

Performance Parameter

1. Permeation

Test Chemicals	Code	Sample 1 Breakthrough [min]	Sample 2 Breakthrough [min]	Sample 3 Breakthrough [min]
Isopropanol (70%)	-/-	197	106	168
n-Heptane	J	> 480	> 480	> 480
Hydrogen peroxide (30%)	P	46 - 60	46 - 60	46 - 60
Formaldehyde (37%)	T	> 480	> 480	> 480
Sodium hydroxide (40%)	K	> 480	> 480	> 480

2. Degradation

Test Chemicals	Code	Degradation [%]	Standard deviation [%]
Isopropanol (70%)	-/-	77.4	1.5
N-Heptane	J	25.6	5.9
Hydrogen peroxide (30%)	P	39.9	6.4
Formaldehyde (37%)	T	29.5	15.2
Sodium hydroxide (40%)	K	10.7	18.0

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3. Permeation Chemotherapy

Test Chemicals	Amount	Breakthrough (minimum) Detection Time [minutes]	Average Steady State Perm. Rate [$\mu\text{g}/\text{cm}^2/\text{minute}$]
Carmustine	3.3 mg/ml (3,300 ppm)	56.5	0.2
Cisplatin	1 mg/ml (1,000 ppm)	> 240 min.	N/A
Cyclophosphamide	20 mg/ml (20,000 ppm)	> 240 min.	N/A
Decarbazine	10 mg/ml (10,000 ppm)	> 240 min.	N/A
Doxorubicin HCl	2 mg/ml (2,000 ppm)	> 240 min.	N/A
Etoposide	20 mg/ml (20,000 ppm)	> 240 min.	N/A
Fluorouracil	50 mg/ml (50,000 ppm)	> 240 min.	N/A
Ifosfamide	50 mg/ml (50,000 ppm)	> 240 min.	N/A
Mitoxantrone	1 mg/ml (1,000 ppm)	> 240 min.	N/A
Paclitaxel	6 mg/ml (6,000 ppm)	> 240 min.	N/A
Thiotepa	10 mg/ml (10,000 ppm)	99.4	0.06
Vincristine Sulfate	1 mg/ml (1,000 ppm)	> 240 min.	N/A

4. Microbiological Testing

Sample Identification	Rep	Sample Weight	Sample Area [cm^2]	Extract Volume	Percent Lysis	Grad/ Reactivity
Culture Media Blank	1	N/A	N/A	N/A	0.56 %	0, None
	2	N/A	N/A	N/A	0.23 %	0, None
	3	N/A	N/A	N/A	- 0.79 %	0, None
Positive Control, Polyisoprene Glove	1	0.97	107	17	95 %	4, Severe
	2	0.99	107	17	92 %	4, Severe
	3	1.00	107	17	94 %	4, Severe
Negative Control, High Density Polyethylene (HDPE)	1	1.92	20	9.5	24 %	2, Mild
	2	1.90	20	9.5	20 %	2, Mild
	3	1.94	20	9.5	21 %	2, Mild
13" Cleanroom Nitrile Gloves	1	0.46	88.4	14.7	32 %	2, Mild
	2	0.47	88.4	14.7	32 %	2, Mild
	3	0.49	88.4	14.7	39 %	2, Mild

The test article elicited a Grade 2 (Not more than 50% of the cells lysed; not more than 50% growth inhibition observable) response and therefore does meet the ISO 10993-5 Biocompatibility test requirements.

5. Gamma Irradiation

Minimum Specified Dose:	25 kGy
Maximum Specified Dose:	50 kGy

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