Nitril-Handschuhe CELOS Glove 2.30

pure[11]-Nr.: 1130311, Marke: CELOS

Eigenschaften

- Steril
- Marke: CELOS
- Handschuhtyp: Dünnfilm
- Länge in cm: 31 cm
- Chemikalienbeständigkeit - Typ: Typ B
- Puderfrei
- Material: Nitril
- Texturierte Fingerspitzen
- Zytostatikageeignet
- Silikonfrei
- Vulkanisationsbeschleunigerfrei
- Verpackungsform: paarweise verpackt
- Antistatisch
- AQL (Acceptable Quality Level)-Wert: 0,65
- Chemikalienbeständig gegen Isopropanol (70%): Level 2 (30-60min)
- Im Reinraum hergestellt
- Länge in Inches: 12 In
- Latexfrei
- Niedrigen Endotoxin-Gehalt

Empfohlene Reinraumklassen

ISO 4 | 5 | 6 | 7 | 8 | 9

GMP A/B | C | D

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we care

- Oberflächenbeschaffenheit: griffig
- Rollrand
- Schutz vor Blut und Körpersekreten ISO 16604:2004
- Passform Hand: handspezifisch
- Viren-/Mikroorganismenschutz EN ISO 374-5:2016
- Wandstärke Mittelfinger in mm: 0,12 mm

Material

- Nitril

Verpackung

- 200PAAR

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Produktvarianten

pure[11]-Nr.: 1130311BL7, Nitril-Handschuhe CELOS Glove 2.30

Farbe: Blau; Größe: 7 / VE: 200PAAR

pure[11]-Nr.: 1130311BL10, Nitril-Handschuhe CELOS Glove 2.30

Farbe: Blau; Größe: 10 / VE: 200PAAR

pure[11]-Nr.: 1130311BL6, Nitril-Handschuhe CELOS Glove 2.30

Farbe: Blau; Größe: 6 / VE: 200PAAR

pure[11]-Nr.: 1130311BL6_5, Nitril-Handschuhe CELOS Glove 2.30

Farbe: Blau; Größe: 6,5 / VE: 200PAAR

pure[11]-Nr.: 1130311BL7_5, Nitril-Handschuhe CELOS Glove 2.30

Farbe: Blau; Größe: 7,5 / VE: 200PAAR

pure[11]-Nr.: 1130311BL8, Nitril-Handschuhe CELOS Glove 2.30

Farbe: Blau; Größe: 8 / VE: 200PAAR

pure[11]-Nr.: 1130311BL8_5, Nitril-Handschuhe CELOS Glove 2.30

Farbe: Blau; Größe: 8,5 / VE: 200PAAR

pure[11]-Nr.: 1130311BL9, Nitril-Handschuhe CELOS Glove 2.30

Farbe: Blau; Größe: 9 / VE: 200PAAR

TECHNICAL DATA SHEET

CELOS Nitrile Glove 2.30

CLEANROOM PRODUCTS | PERSONNEL

RECOMMENDED CLEANROOM CLASSES

ISO	3	4	5	6	7	8	9
GMP			A/B		C	D	

PRODUCT INFORMATION

MATERIAL	100 % pure Nitrile
DESIGN	Beaded cuff and micro-textured throughout the glove
APPLICATION	Sterile cleanroom glove for highest requirements
COLOR	Dark blue
CUFF THICKNESS	0.09 mm (+/- 0.01 mm)
PALM THICKNESS	0.11 mm (+/- 0.01 mm)
THICKNESS AT FINGER	0.13 mm (+/- 0.01 mm)
LENGTH	Min. 310 mm
AQL	0.65

TECHNICAL DATA SHEET

CELOS Nitrile Glove 2.30

CELOS®
a pure[11] brand

PRODUCTS

PART NUMBER	VARIANT	SIZE	STYLE	INNER PACKAGING	QUANTITY PER CASE
1130311	**BL**6	6	Sterile	1 pair/1 peel pouch	4 intermediate bags/LDPE
	BL6_5	6.5		10 peel pouches/1 outer bag	carton liner and case
	BL7	7		5 outer bags/1intermediate bag	200 pairs/case
	BL7_5	7.5			
	BL8	8			
	BL8_5	8.5			
	BL9	9			
	BL10	10			

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

PERFORMANCE PARAMETER

		SPECIFICATION	UNIT
Fluoride	F^-	< 0.010	µg/cm²
Chloride	Cl^-	< 0.300	µg/cm²
Nitrite	NO_2^-	< 0.010	µg/cm²
Bromide	Br^-	< 0.010	µg/cm²
Nitrate	NO_3^-	< 0.200	µg/cm²
Phosphate	PO_4^{3-}	< 0.010	µg/cm²
Sulphate	SO_4^{2-}	< 0.050	µg/cm²
Sodium	Na^+	< 0.050	µg/cm²
Calcium	Ca^{2+}	< 0.300	µg/cm²
Magnesium	Mg^{2+}	< 0.010	µg/cm²
Potassium	K^+	< 0.050	µg/cm²
Zinc	Zn^{2+}	< 0.080	µg/cm²
Ammonium	NH_4^+	< 0.050	µg/cm²

PHYSICAL AND CHEMICAL PROPERTIES

	SPECIFICATION	UNIT
Force at Break (after aging)	≥ 6	N
Tensile strength	≥ 14	MPa
Elongation	≥ 400	%
LPC (> 0.5 µm)	< 1,000	Counts/cm^2
NVR (DI water)	< 3.00	µg/cm^2
Silicone oil, amide and DOP-FTIR	Not detected	-
Endotoxin	< 10	Units/gloves

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 prosess, thus reducing allergic reactions.

- Thiruam disulfide
- Dithiocarbamates
- Mercaptobenzothiazole / MBT derivates
- 1.3 - diphenylguanidine
- Duphenylthiourea, dibuthylthiourea
- Formaldehyde
- Bisphenol A
- Bezoisothiazolinine
- Cethylpiridinium Chloride
- Triphenyl phophite, triphenyl phosphate, tricresyl phosphate
- Abietic acid derivates
- Nickel

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	SAMPLE 2	SAMPLE 3
		Breakthrough [min]	Breakthrough [min]	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

3. Permeation Chemotherapy

TEST CHEMICALS	AMOUNT	BREAKTHROUGH (MINIMUM)	AVERAGE STEADY STATE PERM.
		Direction Time [minutes]	Rate [µg/cm2/minute]
Carmustine	3.3 mg/ml (3,300 ppm)	56.5	0.2
Cisplatin	1 mg/ml (1,000 ppm)	> 240	N/A
Cyclophosphamide	20 mg/ml (20,000 ppm)	> 240	N/A
Decarbazine	10 mg/ml (10,000 ppm)	> 240	N/A
Doxorubicin HCl	2 mg/ml (2,000 ppm)	> 240	N/A
Etoposide	20 mg/ml (20,000 ppm)	> 240	N/A
Fluorouracil	50 mg/ml (50,000 ppm)	> 240	N/A
Ifosfamide	50 mg/ml (50,00 ppm)	> 240	N/A
Mitoxantrone	1 mg/ml (1,000 ppm)	> 240	N/A
Paclitaxel	6 mg/ml (6,000 ppm)	> 240	N/A
Thiotepa	10 mg/ml (10,000 ppm)	99.4	0.06
Vincristine Sulfate	1 mg/ml (1,000 ppm)	> 240	N/A

4. Microbiological Testing

SAMPLE IDENTIFICATION	REP	SAMPLE WEIGHT	SAMPLE AREA	EXTRACT VOLUME	PERCENT LYSIS	GRAD/ REACTIVITY
			cm^2		%	
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 elictied 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	MAXIMUM
Specified Dose	25 kGy	50 kGy

FOOD SUITABILITY

This data sheet shall give an overview of results for food contact testing of Cleanroom Nitrile CELOS® Glove 2.30. The results below reflect migration testing in accordance to the test specification § 31 LFGB (German Food and Feed Code). The product complies with the total migration limit as described. According to the kind and extent of tests performed the test item meets the requirements of the test specification LFGB § 31 and is therefore suitable for contact with foodstuff.

PARAMETER	TEST METHOD -STANDARD	RESULT
Sensory analysis	DIN 10955:2024	Pass
Smell transfer		Pass
Transfer of taste		Pass
Overall migration	DIN EN 1186 ff.:2002	See table below
Overall migration, MPPO	DIN EN 1186-13:2002	See table below
Acrylonitrile, migration	DIN EN 13130-3:2004	See table below
1,3-Butadiene, migration	DIN CEN / TS 13130-15:2005	See table below
Formaldehyde, content	DIN CEN / TS 13130-23:2005	See table below
Primary aromatic amines, migration	In-house method HPLC-MS/MS – quantification by MS-0036943:2020	Pass
Color migration of pigmented plastics	BGESUNDHBL 15 (1972): 285	See table below
Metals, total content at decomposition	ICP-OES according to DIN EN ISO 11885; In-house method – quantification by MS-0022823:2023	See table below
Migration of heavy metals, rubber	ISP-MS according to DIN EN IS 17294-2:2023; In-house method - quantification by MS-0022823:2023	See table below
N-nitrosamines and N-nitrosatable substances	DIN EN 12868:2017	Pass
Polycyclic aromatic hydrocarbons (PAH)	AfPS GS 2019:01 PAK:2019	Pass

Sensory analysis

	CONTACT MEDIUM	PASS / FAIL
Smell transfer	Water	Pass
Transfer of taste	Water	Pass

The samples comply with the requirements of § 31 Para. 1 LFGB or Article 3 of Regulation (EC) 1935/2004 and article 4 of Consumer Goods Ordinance 817.023.21 (CH).

Overall migration

	OVERALL MIGRATION	PASS / FAIL
	[mg / dm²]	
Acetic Acid 3 %	1.8	Pass
Ethanol 50 %	8.6	Pass

The samples comply with the limit value for products in contact with food according to the Commission Directives 2006/141/EC and 2006/125/EC.

Overall migration, MPPO

	OVERALL MIGRATION	PASS / FAIL
	[mg / dm²]	
MPPO	< 2.0	Pass

The samples comply with the limit value for products in contact with food according to the Commission Directives 2006/141/EG and 2006/125/EG.

Migration of Acrylonitrile and 1,3 – Butadiene

	ACRYLONITRILE		1,3 – BUTADIENE	
Migration Solution	Oil	Acetic Acid 3 %	Oil	Acetic Acid 3 %
Results (mg / kg)	Not detectable	Not detectable	Not detectable	Not detectable
Pass / Fail	Pass	Pass	Pass	Pass

The samples comply with limit value for products in contact with foodstuffs according to the Regulation (EU) No 10/2011 and Consumer Goods Ordinance 817.023.21 (CH).

Formaldehyde content

	RESULT	PASS / FAIL
	[mg / l]	
Formaldehyde	< 1	Pass

The samples comply with the requirements according to the recommendation of the BfR part XXI „Commodities based on Natural and Synthetic Rubber".

Color migration of pigmented plastics

	CONTACT MEDIUM	PASS / FAIL
Color fastness	Water	Pass
Color fastness	Acetic acid 3 %	Pass
Color fastness	Ethanol 50 %	Pass
Color fastness	Coconut oil	Pass

The samples comply with the recommendation of the BfR part IX „Colourants for colouring plastics and other polymers for consumer goods", „synthetic materials in food transport" respectively Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food, no traces of colour may migrate into the food simulant.

Metals, total content at decomposition

	RESULT	PASS / FAIL
	[%]	
Lead	< 0.0005	Pass
Cadmium	< 0.0005	Pass

The samples comply according to the Regulation (EC) No 1907/2006 (REACH). Duty to communicate on SVHC, if the concentration of elementary lead or cadmium in the article is higher than 0.1% (m/m).

Migration of metals, ruber

	RESULT	MIGRATION SOLUTION	PASS / FAIL	REQUIREMENT
	[mg/kg] food simulant			[C = Category]
Aluminium	0.013	Acetic acid 3 %	Pass	Aluminium content: **C 1/2/3***: max. 1 mg/kg food or food simulant
Lead	< 0.01	Acetic acid 3 %	Pass	Lead impurities: **C 1/2/3*** not detectable (< 0.001 mg/kg food or food simulant)
Zinc	< 2	Acetic acid 3 %	Pass	Zinc content: **C 1/2/3***: 25 mg/kg food or food simulant

***C 1** [Category 1]
– Materials intended to be put in mouth or materials for toys intended to come into contact and with prolonged contact with the skin (longer than 30 s).

***C 2** [Category 2]
– Materials not covered by category 1 with foreseeable contact to skin for longer than 30 seconds (longer term skin contact) or repeated short term skin contact.

***C 3** [Category 3]
– Materials not covered by category 1 or 2 with foreseeable contact to skin up to 30 seconds (short term skin contact).

The samples comply with the requirement according to BfR recommendation XXI „Consumer goods based on natural and synthetic rubber".

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