



Nitril-Handschuhe CELOS Glove 1.10

pure¹¹-Nr.: 1105050, Marke: CELOS

Eigenschaften

- Marke: CELOS
- Handschuhtyp: Dünnsfilm
- Länge in cm: 30 cm
- Chemikalienbeständigkeit - Typ: Typ B
- Puderfrei
- Material: Nitril
- Texturierte Fingerspitzen
- Lebensmittelkonformität
- Silikonfrei
- Vulkanisationsbeschleunigerfrei
- Verpackungsform: Beutel
- Antistatisch
- AQL (Acceptable Quality Level)-Wert: 1,5
- Chemikalienbeständig gegen Aceton: Level 0 (<10min)
- Chemikalienbeständig gegen Isopropanol (70%): Level 1 (10-30min)
- Im Reinraum hergestellt
- Länge in Inches: 11,8 In
- Latexfrei
- Materialzusammensetzung: Reinmaterial

Empfohlene Reinraumklassen

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

GMP C|D

pure¹¹ GmbH

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- Oberflächenbeschaffenheit: griffig
- Reißfestigkeit EN 455-2 ASTM in MPa: 20-30
- Rollrand
- Schutz vor Blut und Körpersekreten ISO 16604:2004
- Passform Hand: beidhändig
- Viren-/Mikroorganismenschutz EN ISO 374-5:2016
- Wandstärke Mittelfinger in mm: 0,12 mm

Material

- Nitril

Verpackung

- 1000STK

Produktvarianten

pure¹¹-Nr.: 1105050WHXXL, Nitril-Handschuhe CELOS Glove 1.10

Farbe: Weiß; Größe: XXL / VE: 1000STK

pure¹¹-Nr.: 1105050WH3XL, Nitril-Handschuhe CELOS Glove 1.10

Farbe: Weiß; Größe: 3XL / VE: 1000STK

pure¹¹-Nr.: 1105050WHL, Nitril-Handschuhe CELOS Glove 1.10

Farbe: Weiß; Größe: L / VE: 1000STK

pure¹¹-Nr.: 1105050WHM, Nitril-Handschuhe CELOS Glove 1.10

Farbe: Weiß; Größe: M / VE: 1000STK

pure¹¹-Nr.: 1105050WHS, Nitril-Handschuhe CELOS Glove 1.10

Farbe: Weiß; Größe: S / VE: 1000STK

pure¹¹-Nr.: 1105050WHXL, Nitril-Handschuhe CELOS Glove 1.10

Farbe: Weiß; Größe: XL / VE: 1000STK

pure¹¹-Nr.: 1105050WHXS, Nitril-Handschuhe CELOS Glove 1.10

Farbe: Weiß; Größe: XS / VE: 1000STK

Cleanroom Nitrile CELOS® Glove 1.10

Parameter	Test method	Result
<i>pH value</i>	<i>DIN EN 420:2010</i>	Measured pH value: 6,4
<i>Dangerous chemicals and micro-organisms</i>	<i>DIN EN 374-1 + A1:2018</i> <i>DIN EN 374-5:2016</i>	Pass
<i>Air-Leak-Test</i>	<i>DIN EN 374-2:2015</i>	Pass
<i>Water-Leak-Test</i>	<i>DIN EN 374-2:2015</i>	Pass
<i>Permeation</i>	<i>DIN EN 16523-1:2015</i>	See table below
<i>Degradation</i>	<i>DIN EN 374-4:2014</i>	See table below

Performance Parameter

1. Permeation

Test chemicals	Code	Sample 1 Breakthrough [min]	Sample 2 Breakthrough [min]	Sample 3 Breakthrough [min]
N-heptane	J	40	34	39
Hydrogen peroxide (30 %)	P	> 480	> 480	> 480
Formaldehyde (37 %)	T	89	58	36
Sodium hydroxide (40 %)	K	> 480	> 480	> 480
Ethanol (70 %)	-/-	17	14	16
2-Propanol (70 %)	-/-	34	45	33
Hydrochloric acid (30 %)	-/-	> 480	> 480	> 480
Sulfuric acid (50 %)	-/-	> 480	> 480	> 480

2. Degradation

Test chemicals	Code	Degradation [%]	Standard deviation [%]
N-heptane	J	- 40,7	62,9
Hydrogen peroxide	P	31,6	6,5
Formaldehyde	T	18,8	36,4
Sodium hydroxide	K	- 24,3	32,4

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Cleanroom Nitrile CELOS® Glove 1.10

Dear Valued Customer,

This data sheet shall give an overview of results for food contact testing of Cleanroom Nitrile CELOS® Glove 1.10. The results below reflect migration testing in according 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 food-stuff.

Parameter	Test method -Standard	Result
Sensory analysis	DIN 10955:2004	
smell transfer		Pass
transfer of taste		Pass
Overall migration	DIN EN 1186 ff.:2002	See table below
Overall migration, Tenax	DIN EN 1186-13:2002	See table below
Acrylonitril, 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 - quantification by HPLC-MS/MS	Pass
Metals, Natural or Synthetic Rubber	MS-0022823:2020	Pass
N-Nitrosamines and N-nitrosatable sub-	DIN EN 12868:2017	Pass
Polycyclic aromatic hydrocarbons (PAK)	AfPS GS 2014:01 PAK:2014	Pass

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Cleanroom Nitrile CELOS® Glove 1.10

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.

Overall migration into Food Simulants

	Overall Migration (mg /dm ²)	Pass / Fail
Acetic Acid 3%	4	Pass
Ethanol 50%	7	Pass
Tenax	<2	Pass

The samples comply with the limit value for products in contact with food according to the Consumer Goods Ordinance or Regulation (EU) No. 10/2011 and any amendments thereto.

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Cleanroom Nitrile CELOS® Glove 1.10

Migration of Acrylonitril and 1,3 – Butadiene

Migration Solution	Acrylonitril		1,3 - Butadiene	
	Oil	Acetic Acid 3%	Oil	Acetic Acid 3%
Results (mg/kg)	< 0,005	< 0,005	< 0,01	<0,01
Pass / Fail	Pass	Pass	Pass	Pass

The samples comply with limit value for products in contact with foodstuffs according to the German Commodity Goods Ordinance respectively Regulation (EU) No 10/2011 and amendments.

Formaldehyde content

	Result (mg /l)	Pass / Fail
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".

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Cleanroom Nitrile CELOS® Glove 1.10

Primary aromatic amines, migration

	Result (mg/kg food simulant)	Migration solution	Pass / Fail
2,5-Dichloraniline	<0,01	Acetic Acid 3 %	Pass
2,4,5-Trichloraniline	<0,01	Acetic Acid 3 %	Pass
4-Chlor-3-methoxyaniline	<0,01	Acetic Acid 3 %	Pass

Metals / Natural or Synthetic Rubber

	Category	Result (%)	Pass / Fail	Requirement
Lead	3	< 0,001	Pass	Zinc content: Categories 1, 2 and 3 commodities max. 0,003% Special Category commodities max. 0,001%
Zinc	3	< 1	Pass	Lead impurities: Categories 1, 2 and 3 commodities max. 3.0% Special Category commodities max. 1.0%

*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).

*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 .

*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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Parameter	Test method -Standard	Result
Sensory analysis	DIN 10955:2004	Pass
Smell transfer		Pass
Transfer of taste		Pass
Overall migration	DIN EN 1186 ff.:2002	See table below
Overall migration, Tenax	DIN EN 1186-13:2002	See table below
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Primary aromatic amines, migration	In-house method - quantification by HPLC-MS/MS	Pass
Metals, Natural or Synthetic Rubber	MS-0022823:2020	Pass
N-nitrosamines and N-nitrosatable substances	DIN EN 12868:2017	Pass
Polycyclic aromatic hydrocarbons (PAH)	AfPS GS 2014:01 PAK:2014	Pass

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Cleanroom Nitrile CELOS[®] Glove 1.10

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.

Overall migration into Food Simulants

	Overall Migration (mg /dm ²)	Pass / Fail
Acetic Acid 3%	4	Pass
Ethanol 50%	7	Pass
Tenax	<2	Pass

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Cleanroom Nitrile CELOS® Glove 1.10

Migration of Acrylonitrile and 1,3 – Butadiene

Migration Solution	Acrylonitrile		1,3 - Butadiene	
	Oil	Acetic Acid 3%	Oil	Acetic Acid 3%
Results (mg/kg)	< 0.005	< 0.005	< 0.01	<0.01
Pass / Fail	Pass	Pass	Pass	Pass

The samples comply with limit value for products in contact with foodstuffs according to the German Commodity Goods Ordinance respectively Regulation (EU) No 10/2011 and amendments.

Formaldehyde content

	Result (mg /l)	Pass / Fail
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".

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Cleanroom Nitrile CELOS® Glove 1.10

Primary aromatic amines, migration

	Result (mg/kg food simulant)	Migration solution	Pass / Fail
2,5-Dichloraniline	<0.01	Acetic Acid 3 %	Pass
2,4,5-Trichloraniline	<0.01	Acetic Acid 3 %	Pass
4-Chlor-3-methoxyaniline	<0.01	Acetic Acid 3 %	Pass

Metals / Natural or Synthetic Rubber

	Category	Result (%)	Pass / Fail	Requirement
Lead	3	< 0.001	Pass	Lead impurities: Categories 1, 2 and 3 commodities max. 0.003% Special Category commodities max. 0.001%
Zinc	3	< 1	Pass	Zinc content: Categories 1, 2 and 3 commodities max. 3.0% Special Category commodities max. 1.0%

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Parameter	Test method	Result
pH value	DIN EN 420:2010	Measured pH value: 6.4
Dangerous chemicals and micro-organisms	DIN EN 374-1 + A1:2018 DIN EN 374-5:2016	Pass
Air-Leak-Test	DIN EN 374-2:2015	Pass
Water-Leak-Test	DIN EN 374-2:2015	Pass
Permeation	DIN EN 16523-1:2015	See table below
Degradation	DIN EN 374-4:2014	See table below

Performance Parameter

1. Permeation

Test chemicals	Code	Sample 1 Breakthrough [min]	Sample 2 Breakthrough [min]	Sample 3 Breakthrough [min]
N-heptane	J	40	34	39
Hydrogen peroxide (30 %)	P	> 480	> 480	> 480
Formaldehyde (37 %)	T	89	58	36
Sodium hydroxide (40 %)	K	> 480	> 480	> 480
Ethanol (70 %)	-/-	17	14	16
2-Propanol (70 %)	-/-	34	45	33
Hydrochloric acid (30 %)	-/-	> 480	> 480	> 480
Sulfuric acid (50 %)	-/-	> 480	> 480	> 480

2. Degradation

Test chemicals	Code	Degradation [%]	Standard deviation [%]
N-heptane	J	- 40.7	62.9
Hydrogen peroxide	P	31.6	6.5
Formaldehyde	T	18.8	36.4
Sodium hydroxide	K	- 24.3	32.4

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CELOS Nitrile Glove 1.10



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
PROCESS	Laundered with 0.2 micron filtered high resistivity DI water and packed in certified cleanroom environment
APPLICATION	Cleanroom glove with best in class fit and for highest cleanliness requirements
LENGTH	300 mm
CUFF THICKNESS	0.08 mm (+/-0.02 mm)
PALM THICKNESS	0.10 mm (+/-0.02 mm)
FINGERTIP THICKNESS	0.13 mm (+/-0.02 mm)
COLOR	Natural white
CHEM. PERFORMANCE	TYPE B, JKPT, VIRUS

CELOS Nitrile Glove 1.10

PRODUCTS

PART NUMBER	VARIANT	SIZE	STYLE	INNER PACKAGING	OUTER PACKAGING	QUANTITY PER CASE
1105050	WHXS	XS	Non-sterile	100 pcs/bag	10 bags/OB	1 OB/case
	WHS	S				
	WHM	M				
	WHL	L				
	WHXL	XL				
	WH2XL	2XL				
	WH3XL	3XL				

CHARACTERISTICS

- Personal Protective Equipment - Category III
- Glove of newest generation
- Ambidextrous
- Silicone and latex free
- Unique fit and textured fingertips
- Reduced allergy risk
- High tackiness for great grip
- Cleanroom produced and packaged
- Without plasticizers, phthalates, silicone oil and amide
- No sulphur, accelerator and zinc added during compounding process
- Significantly lower levels of TiO₂
- Higher cleanliness due to no added color pigments

PERFORMANCE PARAMETER

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

PHYSICAL AND CHEMICAL PROPERTIES

	SPECIFICATION	UNIT
Tensile strength	≥ 18	MPa
Elongation	≥ 500	%
Particle count LPC (> 0.5 µm)	< 1,200	counts/cm ²
NVR (DI water)	< 3.00	µg/cm ²
Silicone oil, amide and DOP	Absent	-
Surface resistivity	< 10 ¹¹	ohm/sq
Static decay time	< 0.5	seconds
Tribo electric charge	< 20	volts

ADDITIONAL IMPORTANT PRODUCT INFORMATION

According to the EN 21420:2020 test, it is confirmed that during the production of CELOS gloves 1105050, none of the following chemicals are introduced into the production process, thus reducing allergic reactions.

- Thirum disulfide
- Dithiocarbamates
- Mercaptobenzothiazole / MBT derivatives
- 1,3 - diphenylguanidine
- Duphenylthiourea, dibuthylthiourea
- Formaldehyde
- Bisphenol A
- Bezoisothiazoline
- Cethylpyridinium Chloride
- Triphenyl phosphite, triphenyl phosphate, tricresyl phosphate
- Abietic acid derivatives
- Nickel

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IB Inner Bag OB Outer Bag PCS pieces WH white BL blue



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<i>pH value</i>	<i>DIN EN 420:2010</i>	Measured pH value: 6.4
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Transfer of taste	Water	Pass

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Migration Solution	Acrylonitrile		1,3 - Butadiene	
	Oil	Acetic Acid 3%	Oil	Acetic Acid 3%
Results (mg/kg)	< 0.005	< 0.005	< 0.01	<0.01
Pass / Fail	Pass	Pass	Pass	Pass

The samples comply with limit value for products in contact with foodstuffs according to the German Commodity Goods Ordinance respectively Regulation (EU) No 10/2011 and amendments.

Formaldehyde content

	Result (mg /l)	Pass / Fail
Formaldehyde	< 1	Pass

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4-Chlor-3-methoxyaniline	<0.01	Acetic Acid 3 %	Pass

Metals / Natural or Synthetic Rubber

	Category	Result (%)	Pass / Fail	Requirement
Lead	3	< 0.001	Pass	Lead impurities: Categories 1, 2 and 3 commodities max. 0.003% Special Category commodities max. 0.001%
Zinc	3	< 1	Pass	Zinc content: Categories 1, 2 and 3 commodities max. 3.0% Special Category commodities max. 1.0%

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