SHIELD Scientific B.V.



Empfohlene Reinraumklassen

ISO 7 | 8 | 9

GMP D

SHIELDskin Orange Nitrile 260

pure[11]-Nr.: 1105305, Marke: SHIELD Scientific B.V.

Eigenschaften

- Antistatisch
- AQL (Acceptable Quality Level)-Wert: 0,25
- Chemikalienbeständig gegen Aceton: Level 0 (<10min)
- Chemikalienbeständig gegen Isopropanol (100%): Level 2 (30-60min)
- Chemikalienbeständig gegen Isopropanol (70%): Level 3 (60-120min)
- Chemikalienbeständigkeit - Typ: Typ B
- Handschuhtyp: Dünnfilm
- Länge in cm: 26 cm
- Länge in Inches: 10,2 ln
- Latexfrei
- Material: Nitril/Neopren
- Oberflächenbeschaffenheit: glatt
- Puderfrei
- Reißfestigkeit EN 455-2 ASTM in MPa: 10-20
- Rollrand
- Schutz vor Blut und Körpersekreten ISO 16604:2004
- Texturierte Fingerspitzen
- Passform Hand: beidhändig
- Verpackungsform: Spenderbox

we care

pure[11] GmbH |
Bavariafilmplatz 7 | D-82031 Grünwald
T +49 89 5589434 0
F +49 89 5589434 77
www.pure11.de
info@pure11.de

- Viren-/Mikroorganismenschutz EN ISO 374-5:2016
- Vulkanisationsbeschleunigerfrei
- Wandstärke Mittelfinger in mm: 0,17 mm
- Zytostatikageeignet
- Marke: SHIELD Scientific B.V.

Material

- Nitril/Neopren

Verpackung

- 900STK

Produktvarianten

pure[11]-Nr.: 1105305ORL, SHIELDskin Orange Nitrile 260

Farbe: Orange; Größe: L / VE: 900STK

pure[11]-Nr.: 1105305ORM, SHIELDskin Orange Nitrile 260

Farbe: Orange; Größe: M / VE: 900STK

pure[11]-Nr.: 1105305ORS, SHIELDskin Orange Nitrile 260

Farbe: Orange; Größe: S / VE: 900STK

pure[11]-Nr.: 1105305ORXL, SHIELDskin Orange Nitrile 260

Farbe: Orange; Größe: XL / VE: 900STK

pure[11]-Nr.: 1105305ORXS, SHIELDskin Orange Nitrile 260

Farbe: Orange; Größe: XS / VE: 900STK

SHIELDskin™
A REVOLUTION IN GLOVE TECHNOLOGY

ORANGE
BIOLOGISCHES RISIKO

SHIELDskin™
ORANGE NITRILE™ 260



PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425

MDR Medical Device Class I REGULATION (EU)2017/745

CE 0598

UKCA 0120

ISO 374-1 Type B JKPT

ISO 374-5:2016 Level 3 VIRUS



Generelle Risiken ★★★★★

Biologisches Risiko ★★★★★

Chemikalien Risiko ★★★☆☆

⇒ Unsteriler Schutzhandschuh aus Nitril/Neopren, puderfrei, beidhändig tragbar, extra lange Ausführung (260 mm / 10.2").

⇒ Persönliche Schutzausrüstung KAT III (PSA - Komplexes Design) gemäss Verordnung (EU) 2016/425.

⇒ Registriert als Klasse 1 (MPD) gemäss Medizin Produkte Verordnung (EU) 2017/745.

⇒ In völliger Übereinstimmung mit der neuesten EU PSA Norm zum Schutz gegen Chemikalien, Mikroorganismen und Viren.

BESCHREIBUNG	
Bestandteile	Nitril und Neopren (*Polychloropren und Acrylonitril butadien*).
Design	Orange, beidhändig tragbar, Rollrand, texturierte Fingerspitzen.
Verpackung	90 Handschuhe per Box - 10 Boxen per Karton = 900 Handschuhe.

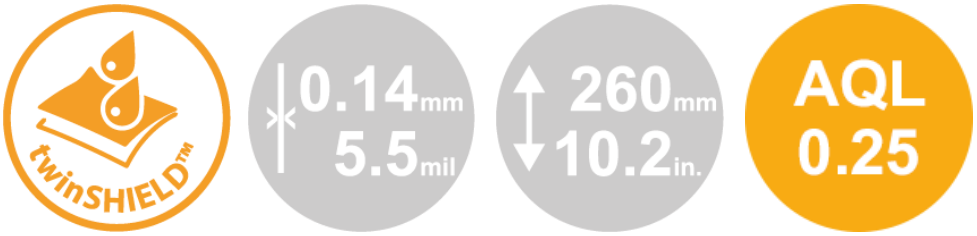
GRÖSSEN	6/XS	7/S	8/M	9/L	10/XL
Artikel Nr.	67 6231	67 6232	67 6233	67 6234	67 6235

NORMEN	
CE/UKCA registrierung	PSA Kategorie III (Komplexes Design) - Verordnung (EU) 2016/425. CE Notified Body No 0598: SGS Fimko Oy, Helsinki - Finnland. UKCA Notified Body No 0120: SGS United Kingdom Ltd, Ellesmere port - United-Kingdom. MP Klasse 1 - Verordnung (EU) 2017/745.
EU PSA normen	ISO 21420:2020+A1:2022, EN 421:2010, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374 -4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018 und ISO 16604:2004 Verfahren B.
EU MP normen	EN 455-1:2020, EN 455-2:2015, EN 455-3:2015 und EN 455-4:2009.
US standards	ASTM D3767-03 (2020), ASTM D573-04 (2019), ASTM D412-16, ASTM D6978-05 (2019).
Weitere standards	EN1149-1/2/3 & 5, ISO 21171:2006, ISO 10993-10:2021.

QUALITÄT	
Qualitätssicherung	Produktionsmanagement gemäss ISO 9001:2015 und ISO 13485:2016. Umweltmanagementsysteme gemäss ISO 14001:2015.
Technologie	twinSHIELD™ doppelwandiger Schutz für einen stärkeren Handschuh und reduziertem Risiko von Mikrolöchern. 2-farbig: orange, zur vereinfachten Auswahl des Handschuhes gemäss des Risikos, kombiniert mit einer sehr angenehmen, weichen Innenlage.

DOKUMENTATION	
Konformitätserklärung	Diese Dokumente können kostenlos von der Produktseite auf unserer Website heruntergeladen werden: www.shieldscientific.com. Für einen einfachen Zugriff scannen Sie den QR-Code.
EU baumuster-prüfbescheinigung	
Benutzerhinweis	

PHYSIKALISCHE EIGENSCHAFTEN



NOMINALE WANDSTÄRKE	mm[1]	mil	Norm
⇒ Finger	0.17	6.7	ASTM D3767-03 (2020)
⇒ Handfläche	0.14	5.5	
⇒ Stulpe	0.10	3.9	

[1] *Wandstärke (+/- 0.03 mm)*

LÄNGE	Minimum	Typischer Wert	Norm
⇒ Spitze Mittelfinger bis Ende Stulpe	≥ 260 mm / 10.2"	265 mm / 10.4"	ISO 21420:2020+A1:2022

REIßFESTIGKEIT	Reißfestigkeit (Spez.)		Äusserste Dehnbarkeit (Spez.)	Reißfestigkeit (typischer Wert)	Norm
⇒ Vor Alterung	≥ 6.0N	14 MPa	≥ 500%	10.0N	EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16
⇒ Nach Alterung	≥ 6.0N	14 MPa	≥ 400%	8.0N	

FESTSTELLUNG "PINHOLES"	Leistungsnachweis	Norm
⇒ Acceptable Quality Level (AQL)	< 0.25[2] - Level 3	ISO 374-2:2019 EN 455-1:2020

[2] *AQL gemäss Definition ISO 2859-1:1999 Probenentnahme.*

SCHUTZLEISTUNG

RISIKEN	Beschreibung	Norm
Mikroorganismen	1000 ml Wasser Test. Leistungslevel 3, AQL < 0.25 (Inspektionslevel G1).	ISO 374-2:2019
Viren	Viren Penetrationstest mit Phi-X174 Bacteriophage gemäss ISO 16604:2004 Verfahren B.	ISO 374-5:2016
Chemikalien	Leistung: Typ B (JKPT). Permeation: Intensiv getestet. Chemikalienbeständigkeitsliste online unter: www.shieldscientific.com. Degradation: auf Degradationsbeständigkeit mit Chemikalien getestet.	ISO 374-1:2016+A1:2018 EN 16523-1:2015+A1:2018 ISO 374-4:2019
Radioaktivität	Schutz vor radioaktiver Kontamination.	EN 421:2010
Zytostatika substanzen	Auf Permeation getestet mit Zytostatika Substanzen durch Dauerkontakt mit der Substanz.	ASTM D6978-05 (2019)
ESD	Antistatisches Verhalten getestet.	EN 1149-1/2/3 & 5

ALLERGIEN	
Bio kompatibilität	Nachgewiesen durch Primary Skin Irritation und Sensitatzions Test gemäss ISO 10993-10:2021 Test.
Vulkanisations-bescheleuniger	Vulkanisationsbeschleuniger frei. Reduziert das Risiko einer Kontakt Dermatitis (Typ IV Allergie/Chemikalien Allergie).
Chemikalien allergie	Nicht nachweisbare Level durch wasserlösliche Extraktion (Phosphate gepufferte Lösung) und High Performance Chromotography (HPLC) Proben Methode für quantitative Analyse.
Puderrück-standswerte	Puderfrei, reduziert die Gefahr auf von Puder verursachter Dermatitis. Puderrückstände (typischer Wert) nicht mehr als 1 mg/HS (Limit = 2 mg/HS) (ISO 21171:2006).
Latex proteine	Latex frei.

SHIELD Scientific
compliance comfort protection
Costerweg 1-B ● 6702 AA Wageningen ● The Netherlands
Phone +31 (0)317 700 202
Email: info@shieldscientific.com
www.shieldscientific.com

SHIELDskin™, ORANGE NITRILE™, twinSHIELD™ and the COLOUR ORANGE are trademarks of SHIELD Scientific. © 2024 Copyright SHIELD Scientific B.V. - All rights reserved.
File: PDS_F_67623X_DE_SHIELDSKIN_ORANGE-NITRILE-260_EXT_FV_016_30062024_SB.pdf

SHIELD Scientific
compliance comfort protection

Chemical resistance guide



LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5	LEVEL 6
< 10 min	10 > 29 min	30 > 59 min	60 > 119 min	120 > 239 min	240 > 479 min	> 480 min

SHIELDskin™ ORANGE NITRILE™ 260

PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425
MDR Medical Device Class I REGULATION (EU)2017/745
CE 0598
ISO 374-1 Type B JKPT



- Length: 260 mm/ 10.2"
- Palm thickness: 0.14 mm/ 5.5 mil
- Chemical performance: Type B
- Biological risk: AQL 0.25 / Level 3
- Particles level: N/A / N/A
- Virus resistant / Chemotherapy drugs
- Allergies: Latex-free / Accelerator-free
- Design: Ambidextrous / Powder-free
- Colour: Orange (outer)/ White (inner)
- ESD - Static dissipative
- Mechanical risk: N/A
- Applications: Laboratory / General workplace / Healthcare

96-48-0 Butyrolactone	LEVEL 2 49 min
67-63-0 Isopropanol 70% at 23°C	LEVEL 3 66 min
79-21-0 Peracetic Acid 10%	LEVEL 4 160 min
5329-14-6 Sulfamic Acid 15%	LEVEL 6 480 min
Mixed Solution Terralin protect	LEVEL 3 103 min
7550-35-8 Lithium bromide 30%	LEVEL 6 480 min DR 22%
7697-37-2 Nitric acid 65%	LEVEL 1 10 min

www.shieldscientific.com
Contact: info@shieldscientific.com
© 2025- Copyright protected SHIELD Scientific - All rights reserved - Printed : 05/02/2025

108-95-2 Phenol aqueous solution 0.45%	LEVEL 6 480 min DR 35%
79-08-3 Bromoacetic acid 7.5%	LEVEL 4 209 min
64-19-7 Acetic acid 99%	LEVEL 0 7 min
67-56-1 Methanol 20%	LEVEL 3 75 min
Mixed Solution LiPF6	LEVEL 6 480 min
79-11-8 Chloroacetic acid 80%	LEVEL 3 75 min
584-84-9 Toluene diisocyanate 95%	LEVEL 0 0 min
64742-49-0 Petroleum benzene 80-100°C	LEVEL 6 480 min
Mixed Solution Neopredisan 135-1	LEVEL 1 20 min
548-62-9 Crystal violet	LEVEL 6 480 min
95-54-4 O-Phenylenediamine	LEVEL 5 308 min
108-95-2 Phenol 4%	LEVEL 1 22 min
72-57-1 Trypan blue	LEVEL 6 480 min
314-13-6 Evans blue	LEVEL 6 480 min

© 2025- Copyright protected SHIELD Scientific - All rights reserved - Printed : 05/02/2025

91-95-2 Diaminobenzidine	LEVEL 6 480 min
3761-53-3 Ponceau 2R	LEVEL 6 480 min
6226-79-5 Ponceau S	LEVEL 6 480 min
Mixed Solution Phenol:Chloroform Isoamyl Alcohol 25:24:1	LEVEL 0 1 min
123-38-6 Propionaldehyde 97%	LEVEL 0 2 min
Mixed Solution Bacillol AF	LEVEL 2 50 min
Mixed Solution Bacillol 30 Foam	LEVEL 3 73 min
66-81-9 Cycloheximide	LEVEL 6 480 min
Mixed Solution Hydranal ® -Composite 2	LEVEL 6 480 min
8007-56-5 Aqua regia	LEVEL 6 480 min
Mixed Solution Euro 95 unleaded petrol	LEVEL 1 10 min
Mixed Solution Mucocit®-T branded mixture	LEVEL 6 480 min
50-01-1 Guanidine hydrochloride	LEVEL 6 480 min
127-18-4 Tetrachloroethylene 99%	LEVEL 0 5 min

© 2025- Copyright protected SHIELD Scientific - All rights reserved - Printed : 05/02/2025

10127-02-3 Acridine orange	LEVEL 6 480 min
111-76-2 2-Butoxyethanol 99%	LEVEL 1 23 min
108-20-3 Diisopropyl ether 99%	LEVEL 1 16 min
79-10-7 Acrylic acid 99%	LEVEL 0 4 min
7726-95-6 Bromine	LEVEL 0 6 min
37143-54-7 1-Methoxy-2-propylamine 95%	LEVEL 0 3 min
108-67-8 1,3,5-Trimethylbenzene 98%	LEVEL 1 10 min
60-24-2 2-Mercaptoethanol 99%	LEVEL 0 1 min
95-63-6 1,2,4- Trimethylbenzene 98%	LEVEL 1 13 min
75-56-9 Propylene oxide 99%	LEVEL 0 0 min
7803-57-8 Hydrazine monohydrate 98%	LEVEL 4 180 min
78-83-1 Isobutanol 99%	LEVEL 3 76 min
77-86-1 Tris (hydroxymethyl) aminomethane Sat. solution	LEVEL 6 480 min
598-75-4 Secondary isoamyl alcohol 98%	LEVEL 2 55 min

© 2025- Copyright protected SHIELD Scientific - All rights reserved - Printed : 05/02/2025

127-09-3
Sodium acetate Sat. solution
LEVEL 6
480 min

7664-93-9
Sulphuric Acid 50%
LEVEL 6
480 min

7664-93-9
Sulphuric Acid 95%-98%
LEVEL 0
8 min

108-87-2
Methylcyclohexane 99.9%
LEVEL 2
55 min

62-53-3
Aniline 99.9%
LEVEL 1
10 min

97-88-1
Butyl methacrylate 99.9%
LEVEL 1
10 min

96-47-9
2-Methyltetrahydrofuran 99.9%
LEVEL 0
1 min

67-68-5
Dimethyl sulfoxide 99% (DMSO)
LEVEL 2
48 min

75-12-7
Formamide 99%
LEVEL 3
99 min

108-95-2
Phenol 0.1% solution
LEVEL 6
480 min

75-59-2
Tetramethylammonium hydroxide 2.5%
LEVEL 6
480 min

109-66-0
n-Pentane 98%
LEVEL 2
56 min

108-94-1
Cyclohexanone 99%
LEVEL 0
5 min

110-54-3
n-Hexane 95%
LEVEL 3
97 min

© 2025- Copyright protected SHIELD Scientific - All rights reserved - Printed : 05/02/2025

71-23-8
n-Propanol
LEVEL 2
46 min

127-19-5
Dimethyl acetamide 99%
LEVEL 0
8 min

60-29-7
Diethyl ether 99%
LEVEL 0
2 min

75-15-0
Carbon disulfide 99.9%
LEVEL 0
0 min

108-39-4
m-Cresol 98.5%
LEVEL 2
57 min

76-03-9
Trichloroacetic acid 10%
LEVEL 6
480 min

7803-57-8
Hydrazine monohydrate 80%
LEVEL 5
430 min

123-91-1
Dioxane 99%
LEVEL 0
4 min

1634-04-4
Methyl Tert Butyl Esther (MTBE)
LEVEL 1
11 min

7664-93-9
Sulphuric Acid 10%
LEVEL 6
480 min

76-05-1
Trifluoroacetic acid 99%
LEVEL 0
1 min

67-64-1
Acetone 99.8%
LEVEL 0
1 min

7681-52-9
Sodium Hypochlorite 13%
LEVEL 6
480 min

1310-58-3
Potassium Hydroxide 40%
LEVEL 6
480 min

© 2025- Copyright protected SHIELD Scientific - All rights reserved - Printed : 05/02/2025

54-11-5
Nicotine 98%

LEVEL 4
151 min

67-63-0
Isopropanol 70%

LEVEL 3
66 min

7722-84-1
Hydrogen peroxide 12%

LEVEL 6
480 min

77-92-9
Citric acid 30%

LEVEL 6
480 min

1330-20-7
Xylene 98.5%

LEVEL 0
4 min

121-44-8
Triethylamine 99%

LEVEL 1
23 min

108-88-3
Toluene 99.9%

LEVEL 0
1 min

109-99-9
Tetrahydrofuran 99.9%

LEVEL 0
0 min

100-42-5
Styrene 99.9%

LEVEL 0
0 min

1310-73-2
Sodium Hydroxide 50%

LEVEL 6
480 min

1310-73-2
Sodium Hydroxide 40%

LEVEL 6
480 min
DR -7%

110-86-1
Pyridine

LEVEL 0
1 min

7664-38-2
Phosphoric acid 85%

LEVEL 6
480 min

7664-38-2
Phosphoric Acid 30%

LEVEL 6
480 min

© 2025- Copyright protected SHIELD Scientific - All rights reserved - Printed : 05/02/2025

108-95-2
Phenol 50%

LEVEL 1
23 min

7697-37-2
Nitric Acid 70%

LEVEL 0
5 min

7697-37-2
Nitric Acid, 50%

LEVEL 2
54 min

872-50-4
N-methyl-2-pyrrolidone

LEVEL 2
32 min

80-62-6
Methyl Methacrylate 99%

LEVEL 0
2 min

75-09-2
Dichloromethane 99%

LEVEL 0
0 min

108-10-1
Methyl Isobutyl Ketone 99%

LEVEL 0
1 min

67-56-1
Methanol 99.9%

LEVEL 0
5 min

67-63-0
Isopropanol 100%

LEVEL 2
46 min

540-84-1
Iso-Octane 99%

LEVEL 6
480 min

7722-84-1
Hydrogen peroxide 30%

LEVEL 6
480 min
DR 27%

7664-39-3
Hydrofluoric acid 48%

LEVEL 0
5 min

7664-39-3
Hydrofluoric acid 40%

LEVEL 1
12 min

7647-01-0
Hydrochloric acid 37%

LEVEL 4
130 min

© 2025- Copyright protected SHIELD Scientific - All rights reserved - Printed : 05/02/2025

999-97-3 Hexamethyldisilizan 99%	LEVEL 6 480 min
142-82-5 n-Heptane 99%	LEVEL 3 91 min DR 47%
111-30-8 Glutaraldehyde 25%	LEVEL 6 480 min
64-18-6 Formic acid 98.5%	LEVEL 0 4 min
50-00-0 Formaldehyde 37%	LEVEL 6 480 min DR 36%
50-00-0 Formaldehyde 10%	LEVEL 6 480 min
141-78-6 Ethyl acetate 99.8%	LEVEL 0 0 min
1239-45-8 Ethidium bromide 5%	LEVEL 6 480 min
64-17-5 Ethanol 70%	LEVEL 2 34 min
64-17-5 Ethanol 99.8%	LEVEL 1 20 min
68-12-2 Dimethyl formamide 99%	LEVEL 0 4 min
109-89-7 Diethylamine 99.5%	LEVEL 0 1 min
110-82-7 Cyclohexane	LEVEL 6 480 min
67-66-3 Chloroform 99.8%	LEVEL 0 0 min

© 2025- Copyright protected SHIELD Scientific - All rights reserved - Printed : 05/02/2025

71-36-3 Butanol 100%	LEVEL 2 44 min
74-97-5 Bromochloromethane	LEVEL 3 74 min
100-51-6 Benzyl alcohol	LEVEL 1 10 min
1336-21-6 Ammonium hydroxide 25%	LEVEL 2 31 min
107-13-1 Acrylonitrile 99%	LEVEL 0 0 min
79-06-1 Acrylamide 40%	LEVEL 6 480 min
75-05-8 Acetonitrile 99.9%	LEVEL 0 0 min
107-06-2 1,2-Dichloroethane 99%	LEVEL 0 2 min

DISCLAIMER: The data provided was based on gloves tested under laboratory conditions, in accordance with EN 16523-1:2015 (formerly EN 374-3:2003) and EN 374-4:2013. The information is for guidance only and may not reflect the user's application. A risk assessment should always be made by purchaser to assess the suitability of gloves for a specific application.

© 2025- Copyright protected SHIELD Scientific - All rights reserved - Printed : 05/02/2025

SHIELD Scientific compliance comfort protection		EU DECLARATION OF CONFORMITY	
Originator: J.F ROBLES	**Revision N°:** 016	**Revision date:** 13.11.2024	**Validity date:** 26/02/2025

Product	SHIELDskin™ ORANGE NITRILE™ 260
Description	Powder-free extra Length ambidextrous non-sterile 26 cm nitrile gloves
Classification	Medical Device Class 1 / Personal Protective Equipment (PPE) Category III (Complex Design)

Product codes	Sizes
67 6231	6/XS
67 6232	7/S
67 6233	8/M
67 6234	9/L
67 6235	10/XL
N/A	N/A
N/A	N/A
N/A	N/A
N/A	N/A

The manufacturer established in the Union:

SHIELD Scientific B.V.

(Dr Willem Dreeslaan 1 – 6721 ND BENNEKOM – THE NETHERLANDS)

declares under his/her sole responsibility that the PPE (product codes as mentioned above) described hereafter:

SHIELDskin™

ORANGE NITRILE™ 260

is in conformity with the provisions of the Medical Device Regulation (EU) 2017/745 and with the national standards transposing harmonized standards EN 455-1:2020+A1:2022, EN 455-2:2015, EN 455-3:2015 & EN 455-4:2009 . It is selfcertified as a Medical Device Class 1. Single Registration Number (SRN) NL-MF-000001691 and Basic UDI-DI 87196320767623XXG refer.

is in conformity with the provisions of Regulation (EU) 2016/425 and with the harmonized standards EN ISO 374-1:2016 + A1:2018 (as a Type B glove against reagents: J, K, P & T) EN ISO 374-5:2016 & EN 420:2003+A1:2009 as well as test method ISO 374-2:2019 (performance level 3), including protection against viruses (ISO 16604:2004), EN 16523-1:2015 + A1:2018 & EN ISO 374-4:2019. . This device is identical to the PPE, which is the subject of EU Type Examination (Module B) certificate of conformity no. FI18/962117 issued by the Notified Body:

SGS FIMKO OY (Notified Body No: 0598) Takomotie 8, FI-00380 Helsinki, Finland

This device is subject to the procedure set out in Annex VIII (ModuleC2) of the Regulation under the surveillance of the Notified Body:

SGS FIMKO OY (Notified Body No: 0598) Takomotie 8, FI-00380 Helsinki, Finland

J.F ROBLES
General Manager
Date: 13.11.2024
Place: Bennekom

