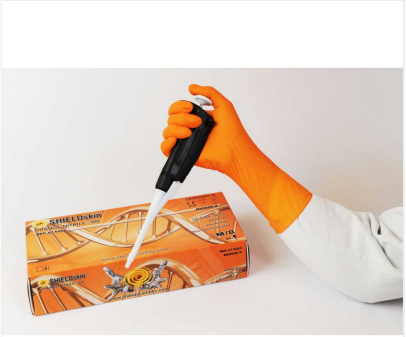


SHIELDskin Orange Nitrile 300

pure11-Nr.: 05306, Hersteller: Shield Scientific

Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105306
- Material: Nitril/Neopren
- Beidhändig tragbar
- Puderfrei
- Latexfrei
- AQL-Wert (Acceptable Quality Level): 0.65
- Texturierte Fingerspitzen
- Vulkanisationsbeschleunigerfrei
- Erstklassige Multi-Polymer Formulation: Acrylonitrile Butadiene (Nitrile) und Polychloropren (Neopren)
- Basierend auf der Twinshield™ Technologie
- Weiße Innenseite
- ESD-Eigenschaften nach EN1149-1,-2,-3 und -5 getestet
- Beständig gegen eine Vielzahl von Zytostatika
- Intensiv auf Chemikalienpermeation getestet nach EN374-3:2003
- Einfache Wandstärke 0,17 mm (Mittelfinger)
- Reduziertes Allergierisiko (Type I & Type IV)
- Viren- und mikroorganismenresistent
- Lebensmittelkonformität nach ED1186-1,-9,-14 geprüft

Empfohlene Reinraumklassen

ISO	3	4	5	6	7	8	9
GMP						D	

Produktvarianten

pure11 GmbH
Bavariafilmplatz 7 | D-82031 Grünwald
Geschäftsführer: Gitte Hansen, Julian Kropp
AG München HRB 171307

T +49 89 5589434 0
F +49 89 5589434 77
www.pure11.de
info@pure11.de

pure11-Nr.: 05306XS
Farbe: Orange / Größe: XS / Herst.-Nr.: 676251 / VE: 500 Stück

pure11-Nr.: 05306S
Farbe: Orange / Größe: S / Herst.-Nr.: 676252 / VE: 500 Stück

pure11-Nr.: 05306M
Farbe: Orange / Größe: M / Herst.-Nr.: 676253 / VE: 500 Stück

pure11-Nr.: 05306L
Farbe: Orange / Größe: L / Herst.-Nr.: 676254 / VE: 500 Stück

pure11-Nr.: 05306XL
Farbe: Orange / Größe: XL / Herst.-Nr.: 676255 / VE: 500 Stück

pure11 GmbH
Bavariafilmplatz 7 | D-82031 Grünwald
Geschäftsführer: Gitte Hansen, Julian Kropp
AG München HRB 171307

T +49 89 5589434 0
F +49 89 5589434 77
www.pure11.de
info@pure11.de

SHIELDskin™
A REVOLUTION IN GLOVE TECHNOLOGY

ORANGE
BIOLOGICAL RISK

SHIELDskin™
ORANGE NITRILE™ 300

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

ISO 374-5:2016
Level 3
VIRUS

General Risk ★★★★★

Biological Risk ★★★★★

Chemical Risk ★★★☆☆

⇒ Powder-free ambidextrous extra length (300 mm / 11.8") non-sterile nitrile/neoprene protective gloves.

⇒ Personal Protective Equipment Category III (PPE - Complex Design) according to Regulation (EU) 2016/425.

⇒ Medical Device Class 1 (MDR) according to the Regulation (EU) 2017/745.

⇒ Fully compliant to the latest EU PPE norms relating to protective gloves against chemicals, micro-organisms and viruses.

DESCRIPTION	
Formulation	Nitrile and neoprene synthetic rubber (*acrylonitrile butadiene and polychloroprene*).
Design	Orange, ambidextrous, beaded cuff, textured fingertips.
Packaging	50 gloves per dispenser - 10 dispensers per carton.

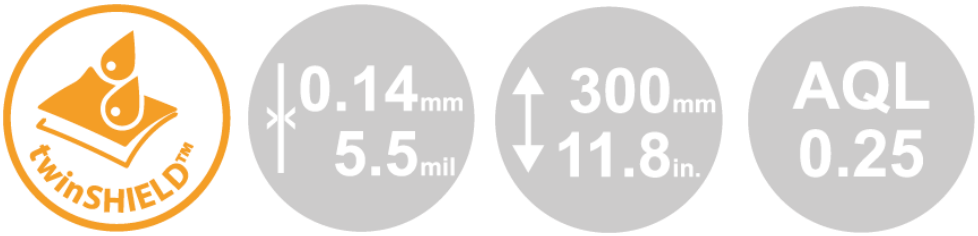
SIZES	6/XS	7/S	8/M	9/L	10/XL	11/XXL
Codes	67 6251	67 6252	67 6253	67 6254	67 6255	67 6256

STANDARDS	
CE registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND. MDR Class 1 - Regulation (EU) 2017/745.
EU PPE norms	ISO 21420:2020, 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 and ISO 16604:2004 Procedure B.
EU MDR norms	EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009.
USA standards	ASTM D3767-03 (2020), ASTM D573-04 (2019), ASTM D412-16, ASTM D6978-05 (2019).
Other standards	EN1149-1/2/3 & 5, ISO 21171:2006, ISO 10993-10:2010.

QUALITY	
Quality assurance	Production management in accordance with ISO 9001:2015 and ISO 13485:2016.
Technology	twinSHIELD™ double-walled protection to offer a stronger glove and to reduce risk of pinholes. Two colours: orange to make it easier to select according to the risk, combined with a soft and comfortable white interior.

DOCUMENTATION	
Declaration of conformity	These documents can be freely downloaded from the product page on our website: www.shieldscientific.com.
EU type examination certificate	For easy access, scan the QR code.
User's instructions	

PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm[1]	mil	Norm
⇒ Finger	0.17	6.7	ASTM D3767-03 (2020)
⇒ Palm	0.14	5.5	
⇒ Cuff	0.10	3.9	

[1] *Thickness (+/- 0.03 mm)*

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 290 mm / 11.4"	300 mm / 11.8"	ISO 21420:2020

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
⇒ Before aging	≥ 6.0N	14 MPa	≥ 500%	10.0N	EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16
⇒ After aging	≥ 6.0N	14 MPa	≥ 400%	8.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 0.25[2] - Level 3	ISO 374-2:2019 EN 455-1:2000

[2] *AQL as defined per ISO 2859-1:1999 for sampling by attributes.*

PROTECTION PROPERTIES

RISKS	Description	Norm
Micro-organisms	1000 ml water test. Performance level 3, AQL < 0.25 (inspection level G1).	ISO 374-2:2019
Viruses	Viral penetration test using Phi-X174 bacteriophage according to ISO 16604:2004 Procedure B.	ISO 374-5:2016
Chemicals	Performance: Type B (JKPT). Permeation: Extensively tested. Online chemical resistance guide on www.shieldscientific.com. Degradation: Tested for determination of resistance to degradation by chemicals.	ISO 374-1:2016+A1:2018 EN 16523-1:2015+A1:2018 ISO 374-4:2019
Radioactivity	Protection from radioactive contamination.	EN 421:2010
Cytotoxic	Tested for permeation to potentially hazardous cancer chemotherapy drugs under conditions of continuous contact.	ASTM D6978-05 (2019)
ESD	Tested for electrostatic properties.	EN 1149-1/2/3 & 5

ALLERGIES	
Bio-compatibility	Demonstrated by skin irritation and sensitization tests in accordance with ISO 10993-10:2010.
Accelerators	Accelerator-free to minimize the risk of allergic contact dermatitis (also known as Type IV, delayed hypersensitivity or chemical allergy).
Chemical allergens	Non-detectable levels using aqueous solution extraction (Phosphate buffered solution) and High Performance Liquid Chromatography (HPLC) assay method for quantitative analysis.
Residual powder	Powder-free to minimize the potential consequences of powder-borne dermatitis. Residual powder content is 1.0 mg/glove (typical) with a limit of 2.0 mg/glove (ISO 21171:2006).
Latex protein	Latex-free.

SHIELD Scientific
compliance comfort protection

Dr. Willem Dreeslaan 1 ● 6721 ND Bennekom ● The Netherlands
Phone +31 (0)317 700 202 ● Fax +31 (0)318 503 742
E-mail: Info@shieldscientific.com
www.shieldscientific.com

File: PDS_F_67625X_EN_SHIELDSKIN_ORANGE-NITRILE-300_EXT_FV_014_15092020_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 - 30 min	30 - 60 min	60 - 120 min	120 - 240 min	240 - 480 min	> 480 min

SHIELDskin* ORANGE NITRILE* 300

PPE Personal Protective Equipment Category III REGULATION (EU) 2016/425
MDD Medical Device Class I DIRECTIVE 93/42/EEC
CE 0598
ISO 374-1 Type B JKPT

- Category III PPE glove (Regulation (EU) 2016/425)
- Complex Design - For mortal and irreversible risks
- Class 1 MDD glove (Council Directive 93/42/EEC)
- Powder-free orange/white nitrile/polychloroprene glove
- twinSHIELD* double-walled protection
- Ambidextrous
- 300 mm / 0.14 mm (EN 420:2003+A1:2009)
- AQL 0.25 (EN 374-2:2014 Level 3)
- Biological risk (ISO 374-1:2016 VIRUS)
- Viral penetration test (ISO 16604:2004 Procedure B)
- Chemical risk (ISO 374-1:2016+A1:2018 - Type B JKPT)
- Waterproof and for low chemical protection
- Tested for chemical permeation (EN 16523-1:2015+A1:2018)

64-19-7 Acetic Acid 100%	LEVEL 0 8 min
67-64-1 Acetone 99,8%	LEVEL 0 1 min
75-05-8 Acetonitrile 99,9%	LEVEL 0 1 min
10127-02-3 Acridine orange	LEVEL 6 480 min
79-06-1 Acrylamide 40%	LEVEL 6 480 min
79-10-7 Acrylic acid 99%	LEVEL 0 4 min
107-13-1 Acrylonitrile 99%	LEVEL 0 0 min

1336-21-6
Ammonium Hydroxide 25%
LEVEL 2
33 min

62-53-3
Aniline 99,9%
LEVEL 1
14 min

Mixed Solution
Aqua regia
LEVEL 6
480 min

Mixed Solution
Bacillol AF
LEVEL 2
50 min

Mixed Solution
Bacillol 30 Foam
LEVEL 3
73 min

100-51-6
Benzyl Alcohol
LEVEL 1
11 min

7726-95-6
Bromine
LEVEL 0
6 min

79-08-3
Bromoacetic acid 7.5%
LEVEL 4
209 min

74-97-5
Bromochloromethane
LEVEL 3
79 min

71-36-3
Butanol 100%
LEVEL 2
47 min

111-76-2
2-Butoxyethanol 99%
LEVEL 1
23 min

97-88-1
Butyl methacrylate 99,9%
LEVEL 1
11 min

75-15-0
Carbon Disulfide 99,9%
LEVEL 0
0 min

67-66-3
Chloroform 99,8%
LEVEL 0
0 min

77-92-9 Citric acid 30%	LEVEL 6 480 min
548-62-9 Crystal violet	LEVEL 6 480 min
110-82-7 Cyclohexane	LEVEL 6 480 min
108-94-1 Cyclohexanone 99%	LEVEL 0 6 min
66-81-9 Cycloheximide	LEVEL 6 480 min
91-95-2 Diaminobenzidine	LEVEL 6 480 min
107-06-2 1,2-Dichloroethane 99%	LEVEL 0 2 min
75-09-2 Dichloromethane 99%	LEVEL 0 0 min
109-89-7 Diethylamine 99,5%	LEVEL 0 1 min
60-29-7 Diethyl ether 99%	LEVEL 0 2 min
108-20-3 Diisopropyl Ether 99%	LEVEL 1 16 min
127-19-5 Dimethyl Acetamide 99%	LEVEL 1 10 min
68-12-2 Dimethyl Formamide 99%	LEVEL 0 5 min
67-68-5 Dimethyl Sulfoxide 99% (DMSO)	LEVEL 2 48 min

64-17-5
Ethanol 99.8%

LEVEL 1
22 min

64-17-5
Ethanol 70%

LEVEL 2
34 min

1239-45-8
Ethidium Bromide 5%

LEVEL 6
480 min

141-78-6
Ethyl Acetate 99.8%

LEVEL 0
1 min

107-21-1
Ethylene Glycol

LEVEL 0
0 min

Mixed Solution
Euro 95 unleaded petrol

LEVEL 1
10 min

314-13-6
Evans blue

LEVEL 6
480 min

50-00-0
Formaldehyde 10%

LEVEL 6
480 min

50-00-0
Formaldehyde 37%

LEVEL 6
480 min

75-12-7
Formamide 99%

LEVEL 3
99 min

64-18-6
Formic acid 98,5%

LEVEL 0
4 min

111-30-8
Glutaraldehyde 25%

LEVEL 6
480 min

111-30-8
Gluteraldehyde 2.5%

LEVEL 6
480 min

50-01-1
Guanidine Hydrochloride

LEVEL 6
480 min

999-97-3 Hexamethyldisilizan 99%	LEVEL 6 480 min
Mixed Solution Hydranal ® -Composite 2	LEVEL 6 480 min
7803-57-8 Hydrazine monohydrate 80%	LEVEL 6 480 min
7803-57-8 Hydrazine monohydrate 98%	LEVEL 4 180 min
7647-01-0 Hydrochloric Acid 37%	LEVEL 4 141 min
7664-39-3 Hydrofluoric Acid 40%	LEVEL 1 14 min
7664-39-3 Hydrofluoric Acid 48%	LEVEL 0 6 min
7664-39-3 Hydrogen Fluoride 48%	LEVEL 0 6 min
7722-84-1 Hydrogen Peroxide 30%	LEVEL 6 480 min
7722-84-1 Hydrogen Peroxide 12%	LEVEL 6 480 min
78-83-1 Isobutanol 99%	LEVEL 3 76 min
540-84-1 Iso-Octane 99%	LEVEL 6 480 min
67-63-0 Isopropanol 100%	LEVEL 2 54 min
67-63-0 Isopropanol 70%	LEVEL 3 72 min

Mixed Solution LiPF6	LEVEL 6 480 min
7550-35-8 Lithium bromide 30%	LEVEL 6 480 min DR 22%
108-39-4 m-Cresol 98.5%	LEVEL 2 59 min
60-24-2 2-Mercaptoethanol 99%	LEVEL 0 1 min
67-56-1 Methanol 99,9%	LEVEL 0 6 min
37143-54-7 1-Methoxy-2-propylamine 95%	LEVEL 0 3 min
108-87-2 Methylcyclohexane 99,9%	LEVEL 2 55 min
108-10-1 Methyl Isobutyl Ketone 99%	LEVEL 0 2 min
80-62-6 Methyl Methacrylate 99%	LEVEL 0 3 min
1634-04-4 Methyl Tert Butyl Esther (MTBE)	LEVEL 1 11 min
96-47-9 2-Methyltetrahydrofuran 99,9%	LEVEL 0 1 min
Mixed Solution Mucocit®-T branded mixture	LEVEL 6 480 min
Mixed Solution Neopredisan 135-1	LEVEL 1 20 min
142-82-5 n-Heptane 99%	LEVEL 3 91 min

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

54-11-5
Nicotine 98%
LEVEL 4
151 min

7697-37-2
Nitric Acid, 50%
LEVEL 3
63 min

7697-37-2
Nitric Acid 70%
LEVEL 0
5 min

872-50-4
N-methyl-2-pyrrolidone
LEVEL 2
32 min

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

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

95-54-4
o-Phenylenediamine
LEVEL 5
308 min

79-21-0
Peracetic Acid, 10%
LEVEL 4
160 min

64742-49-0
Petroleum benzene 80-100°C
LEVEL 6
480 min

108-95-2
Phenol 50%
LEVEL 1
24 min

108-95-2
Phenol 4%
LEVEL 1
22 min

108-95-2
Phenol aqueous solution 0.45%
LEVEL 6
480 min
DR 35%

Mixed Solution
Phenol:Chloroform Isoamyl Alcohol 25:24:1
LEVEL 0
1 min

108-95-2 Phenol 0.1% solution	LEVEL 6 480 min
7664-38-2 Phosphoric Acid, 30%	LEVEL 6 480 min
7664-38-2 Phosphoric acid, 85%	LEVEL 6 480 min
3761-53-3 Ponceau 2R	LEVEL 6 480 min
6226-79-5 Ponceau S	LEVEL 6 480 min
1310-58-3 Potassium Hydroxide 40%	LEVEL 6 480 min
123-38-6 Propionaldehyde, 97%	LEVEL 0 2 min
75-56-9 Propylene oxide 99%	LEVEL 0 0 min
110-86-1 Pyridine	LEVEL 0 1 min
598-75-4 Secondary isoamyl alcohol 98%	LEVEL 2 55 min
127-09-3 Sodium acetate Sat. solution	LEVEL 6 480 min
1310-73-2 Sodium Hydroxide 40%	LEVEL 6 480 min
1310-73-2 Sodium Hydroxide, 50%	LEVEL 6 480 min
7681-52-9 Sodium Hypochlorite 13%	LEVEL 6 480 min

100-42-5
Styrene 99.9%
LEVEL 0
0 min

5329-14-6
Sulfamic Acid, 15%
LEVEL 6
480 min

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

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

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

127-18-4
Tetrachloroethylene 99%
LEVEL 0
5 min

109-99-9
Tetrahydrofuran 99.9%
LEVEL 0
0 min

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

108-88-3
Toluene 99,9%
LEVEL 0
1 min

584-84-9
Toluene diisocyanate 95%
LEVEL 0
0 min

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

121-44-8
Triethylamine 99%
LEVEL 2
36 min

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

95-63-6
1,2,4- Trimethylbenzene 98%
LEVEL 1
13 min

108-67-8 1,3,5-Trimethylbenzene 98%	LEVEL 1 10 min
77-86-1 Tris (hydroxymethyl) aminomethane Sat. solution	LEVEL 6 480 min
72-57-1 Trypan blue	LEVEL 6 480 min
1330-20-7 Xylene 98,5%	LEVEL 0 4 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.

EU DECLARATION OF CONFORMITY

FOR MEDICAL DEVICES AND PERSONAL PROTECTIVE EQUIPEMENT

Originator: J.F ROBLES	**Revision:** 10	**Revision date:** 04.10.2018	**Validity date:** 04.10.2023

PRODUCT	SHIELDskin™ ORANGE NITRILE™ 300
DESCRIPTION	Powder Free Extra Length Ambidextrous Non-Sterile 30 cm Nitrile Gloves
CLASSIFICATION	Medical Device Class 1 / Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	Sizes
67 6251	6/XS
67 6252	7/S
67 6253	8/M
67 6254	9/L
67 6255	10/XL
67 6256	11/XXL

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 Medical Device and PPE (product codes as mentioned above) described hereafter:

SHIELDskin™ ORANGE NITRILE™ 300

is in conformity with the provisions of Council Directive 93/42/EEC and with the national standards transposing harmonized standards EN 455-1:2000, EN 455-2:2015, EN 455-3:2015 and EN 455-4:2009. It is self-certified as a Medical Device Class 1.

is in conformity with the provisions of Regulation (EU) 2016/425 and with the harmonized standards EN ISO 374-1:2016 (as a Type B glove against reagents: J, K, P & T), EN 374-2:2014 (performance level 3, including protection against viruses), EN 16523-1:2015, EN 374-4:2013, EN ISO 374-5:2016 and EN 420:2003 + A1:2009. This device is identical to the PPE, which is the subject of EU Type Examination (Module B) certificate of conformity no. GB18/962117 issued by the Notified Body:

SGS FIMKO OY (Notified Body No: 0598)
Särkiniementie 3 - 00211 Helsinki - Finland

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

SGS FIMKO OY (Notified Body No: 0598)
Särkiniementie 3 - 00211 Helsinki - Finland

Signed for and behalf of SHIELD Scientific B.V

J.F ROBLES
General Manager

Date: 04th October 2018
Place: Bennekom
Validity of this declaration: 04th October 2018 until 04th October 2023

ESD CERTIFICATE

Product Description: **SHIELDskin™ ORANGE NITRILE™ 300**
Orange Nitrile gloves, white and orange, non sterile

Certificate Number: 1666/12 and T1210128 **Date: 02.08. 2012**

Test with 3 pairs/6pieces in accordance with
EN1149-1:2006 Protective Clothing - Electrostatic properties

- Part 1: Test method for measurement of **surface resistivity**
  (Certificate 1666/12) samples tested as received

Surface Resistivity Information in accordance with EN1149-1:2006		
	Maximum Ohms in accordance to EN1149-5	**Measured Ohms**
	$2,5 \times 10^9$ Ω	**$4,04 \times 10^8$ Ω**

Air temperature = 23°C ± 1 Relative humidity = 25 % ± 2 %

Test with 3 pairs/6 pieces in accordance with
EN1149-2:1998 Protective Clothing - Electrostatic properties

- Part 2: Test method for measurement of **vertical resistance**
  (Certificate 1666/12) samples tested as received

Vertical Resistance Information in accordance with EN1149-2:1998		
Maximum Ohms In accordance to EN1149-5	Maximum Value in accordance with TRGS 2153 (Technische Regeln für Gefahrstoffe) BG Germany	**Measured Ohms**
Not applicable	$< 10^8$ Ω	**$6,98 \times 10^7$ Ω**

Air temperature = 23°C ± 1 Relative humitiy = 25 % ± 2 %

Test laboratory/Notified Body: Eurotextil d.o.o., 10000 Zagreb, Croatia

In accordance with EN 1149-5:2008 Protective clothing - Electrostatic Properties

- Part 5: **Material performance and design requirements**

The data provided is based on gloves tested under laboratory conditions, in accordance with EN1149-1:2006, EN1149-2:1998, EN1149-3:2004 and EN1149-5:2008. 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. There is no test standard for in-use resistivity which is part of EN1149-5 for gloves.

Test with 3 pcs in accordance with
EN1149-3:2004 Protective Clothing – Electrostatic properties

- Part 3: Test method for **induction decay**
  (Certificate T1210128) samples tested as received
  Dimension of the specimens: samples too small, measurement made with little ring

Induction Decay Information in accordance with EN1149-3:2004		
Shielding Factor S	Electrostatic dissipative if	**Measured Half decay time T50 (S)**
0,00	T50 <4 S	**2,08**

Air temperature = 23°C Relative humidity = 25 %

Test laboratory/Notified Body: Centexbel-Verviers, 4650 Herve, Belgium

In accordance with EN 1149-5:2008 Protective clothing – Electrostatic Properties

- Part 5: **Material performance and design requirements**

SHIELD Scientific B.V.

Cisco ROBLES
General Manager

The data provided is based on gloves tested under laboratory conditions, in accordance with EN1149-1:2006, EN1149-2:1998, EN1149-3:2004 and EN1149-5:2008. 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. There is no test standard for in-use resistivity which is part of EN1149-5 for gloves.

CHEMICAL ANALYTICAL SERVICES

TEST REPORT ASTM D 6978-05

Project No: 104597A

SUBJECT: Permeation testing per ASTM D 6978-05 on sample submitted

SAMPLE: Powder free 6mil ORANGE nitrile glove
(new Twin Tone SHIELDskin™ ORANGE NITRILE™ 300 Sterile,
SHIELDskin™ ORANGE NITRILE™ 260 and 300,
SHIELDskin Xtreme™ ORANGE NITRILE™ 300 gloves)

Test Laboratory: Akron Rubber Development Laboratories Inc
2887 Gilchrist Road
Akron Ohio 44305
UNITED STATES

TEST CHEMICALS:
Test chemicals and their sources are listed in Table 1.

Table 1. List of the Test Chemicals, Sources, and Expiration Dates

Test Chemical	Chemical Source
Carmustine (BCNU)	Bristol-Myers
Cyclophosphamide (Cytoxan)	Sigma
Doxorubicin Hydrochloride	Teva
Fluorouracil	APP
Etoposide (Toposar)	Teva
Paclitaxel (Taxol)	Dabur Oncology
Thiotepa	Sigma Aldrich

COLLECTION MEDIA:
The collection media which were selected are listed in Table 2.

Table 2. Collection Media for Test Chemicals

Test Chemical	Concentration	Collection Medium
Carmustine (BCNU)	3,300 ppm	10% Ethanol Aqueous Solution
Cyclophosphamide (Cytocan)	20,000 ppm	Distilled Water
Doxorubicin Hydrochloride	2,000 ppm	Distilled Water
Fluorouracil	50,000 ppm	9.20 pH Sodium Hydroxide Solution
Etoposide (Toposar)	20,000 ppm	Distilled Water
Paclitaxel (Taxol)	6,000 ppm	30% Methanol Aqueous Solution
Thiotepa	10,000 ppm	Distilled Water

NOTE: The chemotherapy drugs were prepared as required by the ASTM D 6978-05 Standard at 5.2.2.5, page 2, using the highest concentration of the drugs to which a healthcare worker might be exposed during handling as referenced in the most recent edition of the Physician's Desk Reference or the package inserts of the testing drugs.

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Deviation From Standard Test Method:	Used 1" (2.54cm) Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm^2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff
Comments/Other Conditions:	Magnetic stir bar was used in the sampling chamber

DETECTION METHOD OF CHEMICAL PERMEATION; UV/VIS ABSORPTION SPECTROMETRY
Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristics wavelengths is shown in Table 3.

Table 3. Characteristics Wavelengths used in UV/VIS Absorption Spectrometry.

Test Chemical	Wave length (nm)
Carmustine (BCNU)	229
Cyclophosphamide (Cytoxan)	200
Doxorubicin Hydrochloride	232
Fluorouracil	269
Etoposide (Toposar)	205
Paclitaxel (Taxol)	231
Thiotepa	199

SAMPLE CHARACTERISTICS

Table 4. Sample Characteristics

SAMPLE	THICKNESS (mm)	WEIGHT/UNIT AREA (g/m^2)
	Average	
Carmustine (BCNU)	0.089	99.0
Cyclophosphamide (Cytoxan)	0.111	108.1
Doxorubicin Hydrochloride	0.112	108.1
Fluorouracil	0.111	108.1
Etoposide (Toposar)	0.107	108.1
Paclitaxel (Taxol)	0.109	108.1
Thiotepa	0.100	99.0

CALCULATION:

Average permeation rate for each sampling time interval (except time = 0 minutes) was calculated using the equation below:

$$P_i = ((C_i - C_{i-1}) \times V_t) / ((T_i - T\ C_{i-1}) \times A)$$

Where:

P_i = average permeation rate, ug/cm2/min. at time interval $T_i - T_{i-1}$
C_i = concentration of test chemical detected in collection medium, ug/l,at time T_i
V_t = volume of collection medium, l
i = an index number starting with i = 1 for the first sample
T_i = sampling time, minutes
A = area of specimen in contact with the test chemical, cm^2

RESULTS

The permeation test results are listed in Table 5

Table 5 Permeation Test Results:

Test Chemical	Breakthrough* Detection Time	Steady State Permeation Rate
	Minutes	(Avg.)µg/cm²/min.
Carmustine (BCNU) 3,300 ppm/ 3.3 mg/ml	34.0 (37.7, 34.0, 46.8)	0.7 (0.9, 0.9, 0.4)
Cyclophosphamide (Cytoxan) 20,000 ppm/ 20.0 mg/ml	No breakthrough was detected up to 240 minutes	N/A
Doxorubicin Hydrochloride 2,000 ppm/ 2.0 mg/ml	No breakthrough was detected up to 240 minutes	N/A
Fluorouracil 50,000 ppm/ 50.0 mg/ml	No breakthrough was detected up to 240 minutes	N/A
Etoposide (Toposar) 20,000 ppm/ 20.0 mg/ml	No breakthrough was detected up to 240 minutes	N/A
Paclitaxel (Taxol) 6,000 ppm/ 6.0 mg/ml	No breakthrough was detected up to 240 minutes	N/A
Thiotepa 10,000 ppm/ 10.0 mg/ml	166.1 (166.1, 180.8, 166.2)	0.1 (0.1, 0.1, 0.2)

*Breakthrough detection time is the time in minutes measured from the start of the test to the sampling time that immediately precedes the sampling time at which the permeation rate reaches 0.01 µg/ cm²/min.

SHIELD Scientific B.V.

Cisco Robles
General Manager

ANALYTICAL SERVICES

SUBJECT:	Test Report No BAN 178090/1a Amending Test Report No BAN 178090/1 6 August 2013
SAMPLE:	SHIELDskin™ ORANGE NITRILE™ 260 SHIELDskin™ ORANGE NITRILE™ 300 SHIELDskin XTREME™ ORANGE NITRILE™ 300 DI
Test Laboratory:	SGS United Kingdom Ltd. Units 41 & 43, The Listerhills Park of Science and Commerce Campus Road, Bradford BD7 1 HR United Kingdom

CONCLUSION:
The products meet** the overall migration limit as specified in EEC Commission Regulation 10/2011/EC for foodstuffs listed on page 2 and 3 in applications up to the temperature of 40°C (20°C for Iso-octane) for a contact time of 2 hours (30 minutes for Iso-octane). This product is suitable** for contact with foodstuffs as detailed in EEC Council Directive93/11/EEC and Council of Europe Resolution AP (2004) 4.

**If it can be demonstrated by means of an appropriate test that there is no fatty contact with the material

a) Rubber – Overall migration
Method: with reference to EN 1186-1:2002 for selection of conditions and test methods

EN1186-9:2002 aqueous food simulant by total immersion method
EN1186-14:2002 substitute test

Simulant used	Test condition	Result (mg/dm^2) 1	Reporting Limit (mg/dm^2)	Permissible Limit (mg/dm^2)	Result
3% Acetic Acid (W/V) Aqueous Solution	2 hours at 40° C	6.7 *	3.0	10	Pass
10% Ethanol (V/V) Aqueous Solution	2 hours at 40° C	4.4 *	3.0	10	Pass
Fatty Food Substitute					
95% Ethanol	2 hours at 40° C	41.5*	3.0	10	Fail
Iso octane	0.5 hours at 20° C	ND*	3.0	10	Pass

NOTE:
1. mg/dm^2 = milligram per square decimeter
2. °C = degree Celsius
3. ND = Not Detected

Remark:
1. Test condition and simulant were specified by SHIELD Scientfic B.V.
2. * = The test data is based on first migration result only

Sample Received = 5th June 2013

The products meet the overall migration limit as specified in EEC Commission Regulation 10/2011/EC for foodstuffs listed below in applications up to the temperature of 40°C (20°C for Iso-octane) for a contact time of 2 hours (30 minutes for Iso-octane)

Test Conditions:
a) Simulants/test media: 3% Acetic Acid, 10% Ethanol, 95% Ethanol, Iso-octane
b) Temperature: 40°C (20°C for Iso-octane)
c) Time 2 hours (30 minutes for Iso-octane)

Date of Test: 11th July 2013 and 24th July 2013

The products are suitable** for contact with the following food categories of foodstuffs as detailed in EEC Council Directive 85/572/EEC of 19th December 1985.

01 Beverages
01.01, 01.02, 01.03

02 Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares
02.01, 02.02, 02.03, 02.04, 02.05A, 02.05B, 02.06A, 02.06B

03 Chocolate, sugar and products thereof Confectionery products
03.01, 03.02AI, 03.02AII, 03.02BII, 03.03A, 03.03B, 03.03.C

04 Fruit, vegetables and products thereof
04.01, 04.02A, 04.02B, 04.02CI, 04.02CII, 04.03A, 04.03B, 04.03C[1], 04.04, 04.05A, 04.05B, 04.05CI, 04.05CIII

**If it can be demonstrated by means of an appropriate test that there is no fatty contact with the material

06 Animal products and eggs
06.01A[1], 06.01B[1], 06.02, 06.05A, 06.06A, 06.07A, 06.07B, 06.08

07 Milk products
07.01D, 07.04A, 07.05A, 07.05B

08 Miscellaneous products
08.01, 08.02A, 08.03AI, 08.03AII, 08.03BII, 08.04A, 08.04B, 08.05, 08.06A, 08.07[1], 08.08A, 08.08B, 08.10A, 08.10B, 08.11, 08.12, 08.13A, 08.13B[1], 08.14, 08.15, 08.16, 08.17

SHIELD Scientific B.V.

Cisco Robles
General Manager