SHIELDskin Xtreme Sterile White Nitrile 330 DI+

STERIL

Zusammenfassung

- Material: Nitril
- Farbe: Weiß
- Handspezifisch
- Puderfrei
- Latexfrei
- AQL-Wert (Acceptable Quality Level): 0.65
- **Gammasterilisiert**
- Texturierte Handinnenfläche und Fingerspitzen
- Reduziertes Allergierisiko (Type I & Type IV)
- Mikroorganismenresistent
- Typischer Partikelwert <1200 per cm² = 0.5 µm
- Gut geeignet zum Double-Gloving
- Verpackung: paarweise verpackt

Reinraumklassen

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

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SHIELDskin XTREME™ Sterile White Nitrile 330 DI+

Puderfreie, extra lange, DI Wasser gereinigte, handspezifische Nitrile Handschuhe, STERIL, 33 cm lang

PSA Kategorie III (Complex Design) gemäss Council Directive 89/686/EEC

In völliger Übereinstimmung mit der neuesten Version der PSA Norm - EN374:2003 "Handschuhe zum Schutz gegen Chemikalien und Mikroorganismen"

PRODUKT INFORMATION

Grösse	Artikel Nummern	Entsprechen folgenden Normen und Piktogrammen		
5.5	69 8761	EN374:2003	EN374:2003 Level 3	CE 0123*
6.0	69 8762			
6.5	69 8763			
7.0	69 8764	EN420:2003 + A1:2009		
7.5	69 8765	Auch gemäss EN455-1:2000, EN455-2:2009 + A2:2013, EN455-3:2015, EN455-4:2009 bezogen auf Direktive 93/42/EEC Medizin Produkte Verordnung		
8.0	69 8766			
8.5	69 8767			
9.0	69 8768			
10	69 8769			

* TÜV Produkt Service, Ridlestrasse 3, D-80339 München, Germany

Material: Synthetisches Soft-Nitrile-Polymer (Acrylonitrile Butadiene), basierend auf Skin Nitrile™ Technologie. Enthält kein Naturlatex.

Design: Weiss, handspezifisch, Rollrand, texturierte Handinnenfläche und Finger

Verpackung: Verpackung gemäss den Anforderungen im sterilen Produktionsumfeld. Handschuhe paarweise verpackt in einer PE Tasche und verschweisstem PE Beutel („Peel-Pack"). Zwanzig (20) PE Beutel im verschweissten PE Aussenbeutel (2 doppelte PE Aussenverpackungen). Zehn (10) PE Aussenbeutel per doppelwandigem Aussenkarton (um Beschädigungen zu vermeiden). Zweihundert Paar (200) per Karton.

PHYSIKALISCHE EIGENSCHAFTEN

Charakteristik	Wert	Test Methode
Feststellung "Pinholes"	0.65 AQL[1]	EN374:2003

[1] AQL as defined per ISO 2859 for sampling by attributes

Reissfestigkeit	Reissfestigkeit (min)	Typisch	Äusserste Dehnbarkeit	
- Vor Alterung	6.0N, min.	7.0N	500%, min.	EN455-2:2009 + A2:2013, ASTM D573-04(2010) und ASTM D412-06a(2013)
- Nach beschleunigter Alterung	6.0N, min.	8.0N	400%, min.	

PHYSIKALISCHE EIGENSCHAFTEN (weiterführend)

Charakteristik	Wert			Test Methode
Abmessungen	**Messpunkte**	**mm**	**mil**	
- Nominale Dicke (einfache Wandstärke)	Mittel - Finger	0.15	5.9	ASTM D3767-03(2014)
	Handinnen - Fläche	0.12	4.7	
	Manschette	0.10	4.0	
- Länge	330mm, min.		335mm, typischer Messwert	EN420:2003 + A1:2009

Handflächenweite

Nominale Weite (mm)	5.5	6	6.5	7	7.5	8	8.5	9	10	EN420:2003 + A1:2009
(mm)	140	152	165	178	191	203	216	229	254	

Ergebnisse der Reinheitstests:

Extractables						Test Method
		Specification		Typical value		
Particles	Per $cm^2 \geq 0.5\mu m$	<1.200	particles	900	particles	IEST-RP-C005.4

Extractables						Test Method
Ion		Specification		Typical value		
Ammonium	Nh	0.100	ug/cm^2	0.070	ug/cm^2	IEST-RP-CC005.4
Bromide	Br	0.200	ug/cm^2	0.140	ug/cm^2	
Calcium	Ca	0.350	ug/cm^2	0.250	ug/cm^2	
Chloride	Cl	0.350	ug/cm^2	0.250	ug/cm^2	
Copper	Cu	0.050	ug/cm^2	0.030	ug/cm^2	
Fluoride	F	0.200	ug/cm^2	0.140	ug/cm^2	
Iron	Fe	0.050	ug/cm^2	0.030	ug/cm^2	
Magnesium	Mg	0.350	ug/cm^2	0.250	ug/cm^2	
Nitrate	No	0.030	ug/cm^2	0.020	ug/cm^2	
Potassium	K	0.100	ug/cm^2	0.070	ug/cm^2	
Sodium	Na	0.100	ug/cm^2	0.070	ug/cm^2	
Sulfate	So	0.100	ug/cm^2	0.070	ug/cm^2	
Zinc	Zn	0.350	ug/cm^2	0.250	ug/cm^2	

ZUSÄTZLICHE DATEN

- **Biokompatibilität nachgewiesen** durch „Modified Buehler“ und Primärem Haut Irritations Test
- **Nicht nachweissbare Werte von chemischen Allergenen** gemessen mit aus wässriger Lösung Extraktion (PBS/Phosphate buffered solution) und „High Performance Liquid Chromatography“ (HPLC) Prüfmethode für qualitative Analyse
- Frei von **Thiuramen und Thiazolen**: diese Vulkanisationsbeschleuniger werden in der Herstellung nicht verwendet
- **Puderfrei** gemäss EN ISO 21171:2006 („Medizinische Handschuhe – Feststellung der Puderrückstände auf der Oberfläche“) um die potentiellen Gefahren durch das Einatmen von luftgetragenen Puderpartikeln zu vermeiden. Puderrückstandswerte liegen typischer Weise bei ca 1,0 mg/HS mit einem Limit nach oben von 2,0 mg/HS
- **Mikroorganismen- und Virusresistent** – erreicht einen AQL 0.65 gemäss EN374-2:2003 und erfüllt die Kriterien für höchste Resistenz vor Mikroorganismen (AQL <0.65 Inspektionslevel G1 1000 ml Wassertest). Viren Penetrationstest gemäss ASTM F1671-97b bestanden, durchgeführt mit Phi-X 174 Bakteriophage
- Kompatibel für steriles Umfeld da ohne Papierverpackung und durch intensives Nachreinigen nach der Produktion sehr niedrige Rückstandswerte
- **Gammasterilisiert gemäss Sterility Assurance Level (SAL) of 10^{-6},** in Überseinstimmung mit den Richtlinien gemäss ANSI/AAMI/ EN ISO 11137:2006 “Sterilization of Healthcare Products – Radiation”
- **„Low in Endotoxin” mit** <20 EU/pair (EN455-3:2015) nachgewiesen durch “Limulus Amoebocyte Lysate (LAL) kinetic turbidimetric test”
- **FTIR**: Silicone, Amide und DOP (IEST-RP-C005.4) nicht nachweisbar
- **NVR**: maximal 30 mg/g (IEST-RP-C005.4)
- **ESD** Verhalten verhalten getestet nach EN1149-1,-2,-3 und -5
- Intensiv auf **Chemikalienpermeation** getestet nach EN374-3:2003 mit einer grossen Auswahl an Chemikalien (genaue Information zu finden unter: www.shieldscientific.com/public/chemical-resistance-guide

QUALITÄTS SYSTEME

- Herstellung gemäss ISO 9001:2008 und ISO 13485:2003

“SHIELDskin™, A revolution in Glove Technology”

SHIELD Scientific
compliance comfort protection

www.shieldscientific.com

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CHEMICAL RESISTANCE GUIDE

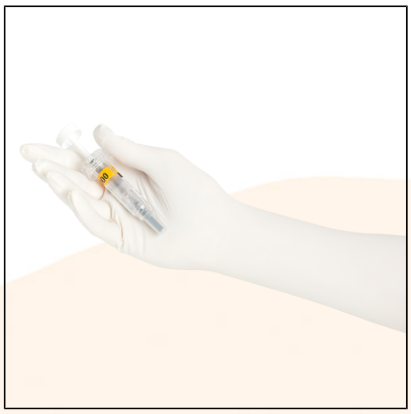
Level 0	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
0 - <10 min	10 - 30 min	30 - 60 min	60 -120 min	120 - 240 min	240 - 480 min	< 480 min

SHIELDskin XTREME* Sterile White Nitrile 330 DI+

CE 0120

EN374:2003 LEVEL 3

EN374:2003



- Category III PPE glove (PPE Directive 89/686/EEC)
- Complex Design - For mortal & irreversible risks
- Powder-free white nitrile glove
- Hand-specific
- 330 mm / 0.12 mm (EN 420:2003 + A1:2009)
- AQL 0.65 (EN 374-2:2003 Level 3)
- Viral penetration test (ASTM F1671-97b)
- Waterproof and for low chemical protection
- Tested for chemical permeation (EN 16523-1:2015 supersedes EN 374-3:2003)
- Typical particle levels: less than 900 per cm² more or equal 0.5µm
- Tested according to EN 1149-1-2-3 & 5
- Type I hypersensivity eliminated - Type IV hypersensivity reduced

6	79-06-1 Acrylamide 40%	480'
6	1239-45-8 Ethidium bromide 5%	480'
6	50-00-0 Formaldehyde, 37%	480'
6	111-30-8 Glutaraldehyde 25%	480'
6	7722-84-1 Hydrogen Peroxide, 30%	480'
6	1310-73-2 Sodium Hydroxide, 40%	480'
6	7681-52-9 Sodium Hypochlorite 13%	480'
6	7664-93-9 Sulphuric acid 50%	480'
4	67-63-0 Isopropanol 70%	155'

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SHIELD Scientific
compliance comfort protection

CHEMICAL RESISTANCE GUIDE

Level 0	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
0 - <10 min	10 - 30 min	30 - 60 min	60 -120 min	120 - 240 min	240 - 480 min	< 480 min

SHIELDskin XTREME* Sterile White Nitrile 330 DI+

3	Mixed Solution Klercide 70/30 sterile IPA	94'
3	64-17-5 Ethanol, 70%	76'
2	Mixed Solution Klercide Premier - WFI 70/30 sterile IPA	55'
2	67-63-0 Isopropanol 100%	44'
1	1336-21-6 Ammonium Hydroxide, 25%	27'
1	142-82-5 Heptane	25'
1	Mixed Solution Klercide Premier - WFI 60/40 sterile Alcohol	23'
1	64-17-5 Ethanol 100%	16'
0	7664-93-9 Sulphuric acid 95%-98%	6'
0	1330-20-7 Xylene 98,5%	3'
0	67-64-1 Acetone 99.8%	1'
0	75-05-8 Acetonitrile 99,9%	1'
0	80-62-6 Methyl Methacrylate 99%	1'

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CHEMICAL RESISTANCE GUIDE

Level 0	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
0 - <10 min	10 - 30 min	30 - 60 min	60 -120 min	120 - 240 min	240 - 480 min	< 480 min

SHIELDskin XTREME* Sterile White Nitrile 330 DI+

0	75-09-2 Dichloromethane 99%	0'
0	109-89-7 Diethylamine 99,5%	0'

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SHIELD Scientific compliance comfort protection	EC Declaration of Conformity for Personal Protective Equipment	Revision: 3 Revision Date: 12.03.12 Originator: J.F. Robles

Product: SHIELDskin XTREME™ Sterile White Nitrile 330 DI+ Powder Free Extra DI washed Pair-packed Hand-specific 33cm Cleanroom Gloves

Product Codes:

SHIELD Scientific codes	Size
69 8761	5.5
69 8762	6
69 8763	6.5
69 8764	7
69 8765	7.5
69 8766	8
69 8767	8.5
69 8768	9
69 8769	10

Classification: PPE Category III (Complex Design)

Applicable Norms: Protective Gloves against Chemicals and Micro-Organisms – Part 1: Terminology and performance requirements (EN374-1: 2003), Part 2: Determination of resistance to penetration (EN374-2: 2003), Part 3: Determination of resistance to permeation by chemicals (EN374-3: 2003) and General Requirements for Gloves (EN420: 2003 + A1:2009).

The manufacturer established in the European Economic Community:

SHIELD Scientific B.V.,
Galvanistraat 1,
6716 AE EDE,
The Netherlands

declares that the Personal Protective Equipment (PPE): Protective Gloves (Product Codes as mentioned above) described hereafter:

SHIELDskin XTREME™ Sterile White Nitrile 330 DI+

is in conformity with the provisions of Council Directive 89/686/EEC and with the harmonized standards EN374-1: 2003, EN374-2: 2003, EN374-3: 2003 and EN420: 2003 + A1: 2009. This device is identical to the PPE, which is the subject of EC certificate of conformity no. G2S 06 11 42866 013 issued by the Notified Body:

TÜV SÜD Product Service GmbH (Notified Body No: 0123),
Ridlerstrasse 65,
80339 MÜNCHEN, Germany.

This device is subject to the procedure set out in Article 11 point B of Directive 89/686/EEC under the supervision of the Notified Body:

TÜV SÜD Product Service GmbH (Notified Body No: 0123),
Ridlerstrasse 65,
80339 MÜNCHEN, Germany.

SHIELD Scientific B.V.

J.F ROBLES
General Manager

Validity of this Declaration: 12th March 2012 until December 31st 2013

CHEMICAL ANALYTICAL SERVICES

TEST REPORT ASTM D 6978-05

Project No: 85202-A

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

SAMPLE: SHIELDskin™ Sterile Nitrile Gloves, 6 mil, lot# 274R08C
(equivalent SHIELDskin Xtreme™ Sterile White Nitrile 330 DI+ gloves (code 69 8761-69 8769)

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

TESTING CHEMOTHERAPY DRUGS:

Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

Test Chemical	Chemical Source	Lot #	Expiration date
Carmustine (BCNU)	Sigma	59H3657	09.2010
Cyclophosphamide (Cytoxan)	Sigma	068K1131	11.2010
Doxorubicin Hydrochloride	Teva	07N625	10.2009
Fluorouracil	APP	203933	04.2010
Etoposide (Toposar)	Teva	31303976B	09.2011
Paclitaxel (Taxol)	Dabur Oncology	PA08H00701	05.2010
Thiotepa	Sigma	078K1526	12.2010

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 (Cytoxan)	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:	Palm area
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. Thickness Characteristics

SAMPLE	THICKNESS (mm)				WEIGHT/UNIT AREA (g/m^2)
	#1	#2	#3	Average	
Carmustine (BCNU)	0.109	0.108	0.113	0.110	108.1
Cyclophosphamide (Cytoxan)	0.107	0.111	0.115	0.111	108.1
Doxorubicin Hydrochloride	0.114	0.111	0.111	0.112	108.1
Fluorouracil	0.111	0.106	0.115	0.111	108.1
Etoposide (Toposar)	0.102	0.110	0.110	0.107	108.1
Paclitaxel (Taxol)	0.106	0.109	0.112	0.109	108.1
Thiotepa	0.104	0.105	0.119	0.109	108.1

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

Table 5. Permeation Test Results:

Test Chemical	**Average Breakthrough* Detection Time**	**Average Steady State Permeation Rate**
	Minutes	**(Avg.)µg/cm^2/min.**
Carmustine (BCNU) 3,300 ppm/ 3.3 mg/ml	4.99 (5.45, 4.67, 4.84)	0.840 (0.710, 0.515, 01.30)
Cyclophosphamide (Cytoxan) 20,000 ppm/ 20.0 mg/ml	No breakthrough was detected up to 240 minutes	0
Doxorubicin Hydrochloride 2,000 ppm/ 2.0 mg/ml	No breakthrough was detected up to 240 minutes	0
Fluorouracil 50,000 ppm/ 50.0 mg/ml	No breakthrough was detected up to 240 minutes	0
Etoposide (Toposar) 20,000 ppm/ 20.0 mg/ml	No breakthrough was detected up to 240 minutes	0
Paclitaxel (Taxol) 6,000 ppm/ 6.0 mg/ml	No breakthrough was detected up to 240 minutes	0
Thiotepa 10,000 ppm/ 10.0 mg/ml	120.3 (147.0, 17.37, 196.61)	0.159 (0.072, 0.325, 0.080)

*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/ **cm**^{2}/min.

SHIELD Scientific B.V.
Date: 20.05.2010

Cisco Robles
General Manager