SHIELDskin Xtreme Sterile Orange Nitrile 300 DI

pure11-Nr.: 05209, Hersteller: Shield Scientific

STERIL ZYTO

Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1105209
- Material: Nitril/Neopren
- Handspezifisch
- Puderfrei
- Latexfrei
- AQL-Wert (Acceptable Quality Level): 0.65
- Gammasterilisiert
- Texturierte Handinnenflächen und Fingerspitzen
- Vulkanisationsbeschleunigerfrei
- Eignet sich perfekt als Unterziehhandschuh
- Einzigartige Skin Nitrile™ Technologie
- Mit weißer Innenseite
- Einfache Wandstärke 0,15 mm (Mittelfinger)
- Reduziertes Allergierisiko (Type IV)
- Viren- und mikroorganismenresistent
- Gut geeignet zum Double-Gloving
- Beständig gegen eine Vielzahl von Zytostatika
- Gute Chemikalienbeständigkeit

Empfohlene Reinraumklassen

ISO	3	4	5	6	7	8	9
GMP			A/B		C	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 clean room consumables

pure11-Nr.: 052095b
Farbe: Orange / Größe: 5,5 / Herst.-Nr.: 696551 / VE: 200 Paar

pure11-Nr.: 052096
Farbe: Orange / Größe: 6,0 / Herst.-Nr.: 696552 / VE: 200 Paar

pure11-Nr.: 052096b
Farbe: Orange / Größe: 6,5 / Herst.-Nr.: 696553 / VE: 200 Paar

pure11-Nr.: 052097
Farbe: Orange / Größe: 7,0 / Herst.-Nr.: 696554 / VE: 200 Paar

pure11-Nr.: 052097b
Farbe: Orange / Größe: 7,5 / Herst.-Nr.: 696555 / VE: 200 Paar

pure11-Nr.: 052098
Farbe: Orange / Größe: 8,0 / Herst.-Nr.: 696556 / VE: 200 Paar

pure11-Nr.: 052098b
Farbe: Orange / Größe: 8,5 / Herst.-Nr.: 696557 / VE: 200 Paar

pure11-Nr.: 052099
Farbe: Orange / Größe: 9,0 / Herst.-Nr.: 696558 / VE: 200 Paar

pure11-Nr.: 0520910
Farbe: Orange / Größe: 10,0 / Herst.-Nr.: 696559 / VE: 200 Paar

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 XTREME™

A REVOLUTION IN GLOVE TECHNOLOGY

Sterile

BIO

CONTAMINATION CONTROL

SHIELDskin XTREME™

Sterile ORANGE NITRILE™ 300 DI

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

CE 0598

ISO 374-1 Type B KPT

ISO 374-5:2016 Level 3 VIRUS

Sterile

Bio contamination control

DI

Basic contamination control

⇒ Powder-free single DI washed hand-specific standard length (300 mm / 11.8") sterile nitrile/ neoprene cleanroom gloves.

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

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

DESCRIPTION	
Formulation	Nitrile and neoprene synthetic rubber (*acrylonitrile butadiene and polychloroprene*).
Design	Orange, hand-specific, beaded cuff, textured palm and fingers.
Packaging	1 pair per PE peel pouch - 20 pouches per sealed poly bag - 10 poly bags per PE bag per carton.

SIZES	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9	10
Codes	69 6551	69 6552	69 6553	69 6554	69 6555	69 6556	69 6557	69 6558	69 6559

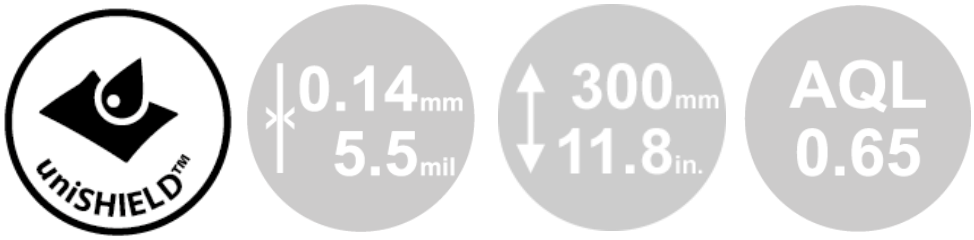
STANDARDS	
CE registration	PPE Category III (Complex Design) - Regulation (EU) 2016/425. Notified Body No 0598: SGS Fimko Oy, Helsinki - FINLAND.
EU PPE norms	ISO 21420:2020, ISO 374-1:2016+A1:2018, ISO 374-2:2019, ISO 374-4:2019, ISO 374-5:2016, EN 16523-1:2015+A1:2018 and ISO 16604:2004 Procedure B.
EU MDR norms[1]	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) and IEST-RP-CC005.4 (2013).
Other standards	ISO 11137-2:2015, ISO 10993-10:2010.

[1] *With reference to Regulation (EU) 2017/425 for Medical Devices*

QUALITY	
Quality assurance	Production management in accordance with ISO 9001:2015 and ISO 13485:2016.
Technology	uniSHIELD™ single-walled protection to offer an ideal compromise between comfort and protection. Synthetic soft polymer, based on Skin Nitrile™ technology with a blend of polychloroprene. Compatible with sterile processing environments due to paperless packaging and multiple post leaching of gloves (single washed in deionised water).

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	
Certificate of conformance	To access CoC and CoI, you need to be registered. Please contact us at info@shieldscientific.com or call your SHIELD Scientific representative.
Certificate of irradiation	

PHYSICAL PROPERTIES



NOMINAL THICKNESS	mm[2]	mil	Norm
⇒ Finger	0.15	5.9	ASTM D3767-03 (2020)
⇒ Palm	0.14	5.5	
⇒ Cuff	0.09	3.5	

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

LENGTH	Minimum	Typical	Norm
⇒ From middle finger tip to edge of cuff	≥ 300 mm / 11.8"	305 mm / 12.0"	ISO 21420:2020

STRENGTH PROPERTIES	Force at break (spec.)		Ultimate elongation (spec.)	Force at break (typical)	Norm
⇒ Before aging	≥ 6.0N	14 MPa	≥ 500%	12.0N	EN 455-2:2015 ASTM D573-04 (2019) & ASTM D412-16
⇒ After aging	≥ 6.0N	14 MPa	≥ 400%	11.0N	

FREEDOM FROM HOLES	Performance	Norm
⇒ Acceptable Quality Level (AQL)	< 0.65[3] - Level 3	ISO 374-2:2019 EN 455-1:2000

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

RISKS	Description	Norm
Micro-organisms	1000 ml water test. Performance level 3, AQL < 0.65 (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 (KPT). 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
Cytotoxic	Tested for permeation to potentially hazardous cancer chemotherapy drugs under conditions of continuous contact.	ASTM D6978-05 (2019)

CLEANLINESS PROPERTIES

PARTICLES	Specification	Typical value	Test method
Particles/cm² ≥ 0.5μm	< 3,000 particles (spec.)	1,000 particles	IEST-RP-CC005.4

EXTRACTABLES (ION)	Specification (μg/cm²)	Typical value (μg/cm²)	Test method
Ammonium (NH_4)	0.050	0.015	IEST-RP-CC005.4
Bromide (Br)	0.030	< 0.008	
Calcium (Ca)	0.500	0.300	
Chloride (Cl)	0.400	0.100	
Fluoride (F)	0.010	< 0.008	
Magnesium (Mg)	0.010	< 0.008	
Nitrate (NO_3)	0.200	0.090	
Nitrite (NO_2)	0.050	< 0.008	
Phosphate (PO_4)	0.050	< 0.008	
Potassium (K)	0.050	0.020	
Sodium (Na)	0.050	0.008	
Sulphate (SO_4)	0.050	0.008	

EXTRA TESTS	Description	Test method
Sterility	Terminally sterilized by gamma irradiation to Sterility Assurance Level (SAL) of 10^{-6} (ISO 11137-2:2015).	
Endotoxins	Low Endotoxin content at < 20 EU/pair demonstrated by Limulus Amoebocyte Lysate (LAL) kinetic turbidimetric test.	EN 455-3:2015
NVR	Maximum 30 μg/g.	IEST-RP-CC005.4
FTIR	Non-detectable levels of silicone, amide and DOP.	IEST-RP-CC005.4
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.
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_69655X_EN_SHIELDSKIN-XTREME_Sterile-ORANGE-NITRILE-300-DI_EXT_FV_009_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 XTREME* Sterile ORANGE NITRILE* 300 DI

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

CE 0598

ISO 374-1 Type B KPT

ISO 374-5:2016 Level 3 VIRUS

- Category III PPE glove (PPE Regulation (EU) 2016/425)
- Complex Design - For mortal & irreversible risks
- Powder-free orange nitrile/polychloroprene glove
- Hand-specific
- 300 mm / 0.14 mm (EN 420:2003+A1:2009)
- Biological risk (ISO 374-5:2016 VIRUS)
- AQL 0.65 (EN 374-2:2014 Level 3)
- Viral penetration test (ISO 16604:2004 Procedure B)
- Chemical risk (ISO 374-1:2016+A1:2018 - Type B KPT)
- Waterproof and for low chemical protection
- Tested for chemical permeation (EN 16523-1:2015+A1:2018)
- Typical particle levels: less than 1000 per cm² more or equal 0.5µm
- Type I hypersensivity eliminated - Type IV hypersensivity reduced

64-19-7 Acetic Acid 100%	LEVEL 0 6 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 1 28 min
62-53-3 Aniline 99,9%	LEVEL 1 14 min

100-51-6 Benzyl Alcohol	LEVEL 0 9 min
74-97-5 Bromochloromethane	LEVEL 3 66 min
71-36-3 Butanol 100%	LEVEL 2 39 min
97-88-1 Butyl methacrylate 99,9%	LEVEL 1 11 min
67-66-3 Chloroform 99,8%	LEVEL 0 0 min
77-92-9 Citric acid 30%	LEVEL 6 480 min
110-82-7 Cyclohexane	LEVEL 6 480 min
108-94-1 Cyclohexanone 99%	LEVEL 0 6 min
75-09-2 Dichloromethane 99%	LEVEL 0 0 min
127-19-5 Dimethyl Acetamide 99%	LEVEL 0 8 min
68-12-2 Dimethyl Formamide 99%	LEVEL 0 4 min
67-68-5 Dimethyl Sulfoxide 99% (DMSO)	LEVEL 2 42 min
64-17-5 Ethanol 99.8%	LEVEL 1 16 min
64-17-5 Ethanol 70%	LEVEL 2 31 min

1239-45-8 Ethidium Bromide 5%	LEVEL 6 480 min
107-21-1 Ethylene Glycol	LEVEL 0 0 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 3 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
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 3 116 min
7664-39-3 Hydrofluoric Acid 40%	LEVEL 1 10 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 DR 22%
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 43 min
67-63-0 Isopropanol 70%	LEVEL 3 61 min
Mixed Solution Klercide Premier - WFI 60/40 sterile Alcohol	LEVEL 2 41 min
Mixed Solution Klercide Premier - WFI 70/30 sterile IPA	LEVEL 3 106 min
Mixed Solution Klercide 70/30 sterile IPA	LEVEL 3 76 min
108-39-4 m-Cresol 98.5%	LEVEL 2 59 min
67-56-1 Methanol 99,9%	LEVEL 0 5 min
37143-54-7 1-Methoxy-2-propylamine 95%	LEVEL 0 3 min
108-87-2 Methylcyclohexane 99,9%	LEVEL 2 55 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

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 2
49 min

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

Mixed Solution
Perform sterile concentrate Oxy 2%
LEVEL 6
480 min

Mixed Solution
Perform sterile concentrate PAA 3%
LEVEL 6
480 min

Mixed Solution
Perform sterile PAA ready to use
LEVEL 6
480 min

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

7664-38-2
Phosphoric Acid, 30%
LEVEL 6
480 min

7664-38-2
Phosphoric acid, 85%
LEVEL 6
480 min

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

Mixed Solution
SPOR-KLENZ Solution

LEVEL 6
480 min

100-42-5
Styrene 99.9%

LEVEL 0
0 min

7664-93-9
Sulphuric Acid 10%

LEVEL 6
480 min

7664-93-9
Sulphuric Acid 95%-98%

LEVEL 0
6 min

7664-93-9
Sulphuric Acid 50%

LEVEL 6
480 min

109-99-9
Tetrahydrofuran 99.9%

LEVEL 0
0 min

76-03-9
Trichloroacetic acid 10%

LEVEL 6
480 min

121-44-8 Triethylamine 99%	LEVEL 2 36 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
1330-20-7 Xylene 98,5%	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.

EU DECLARATION OF CONFORMITY

FOR PERSONAL PROTECTIVE EQUIPEMENT

Originator: J.F ROBLES	**Revision:** 6	**Revision date:** 31.12.2019	**Validity date:** 31.12.2024

PRODUCT	SHIELDskin XTREME™ Sterile ORANGE NITRILE™ 300 DI
DESCRIPTION	Powder Free DI washed Pair-packed Hand-specific 30cm Cleanroom Gloves
CLASSIFICATION	Personal Protective Equipment (PPE) Category III (Complex Design)

SHIELD Scientific codes	**Sizes**
69 6551	5.5
69 6552	6
69 6553	6.5
69 6554	7
69 6555	7.5
69 6556	8
69 6557	8.5
69 6558	9
69 6559	10

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 XTREME™ Sterile ORANGE NITRILE™ 300 DI

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: 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. FI12/123456 (Technical file submitted/Notified Body answer pending)* 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: 31th December 2019
Place: Bennekom
Validity of this declaration: 31th December 2019 until 31th December 2024

CHEMICAL ANALYTICAL SERVICES

TEST REPORT ASTM D 6978-05

Project No: 104597B

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

SAMPLE: SHIELDskin XTREME™ Sterile ORANGE NITRILE™ 300 DI

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	Pfizer
Etoposide (Toposar)	APP
Fluorouracil	APP
Paclitaxel (Taxol)	Teva
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
Etoposide (Toposar)	20,000 ppm	Distilled Water
Fluorouracil	50,000 ppm	9.20 pH Sodium Hydroxide Solution
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"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 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
Etoposide (Toposar)	205
Fluorouracil	269
Paclitaxel (Taxol)	231
Thiotepa	199

SAMPLE CHARACTERISTICS

Table 4. Sample Characteristics

SAMPLE	THICKNESS (mm)	WEIGHT/UNIT AREA (g/m^2)
	Average	
Carmustine	0.089	88.6
Cyclophosphamide (Cytoxan)	0.090	88.6
Doxorubicin Hydrochloride	0.089	88.6
Etoposide (Toposar)	0.086	88.6
Fluorouracil	0.088	88.6
Paclitaxel (Taxol)	0.090	88.6
Thiotepa	0.091	88.6

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	30.8 (46.6, 35.5, 30.8)	0.7 (0.6, 0.9, 0.7)
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
Etoposide (Toposar) 20,000 ppm / 20.0 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
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	106.0 (106.0,136.6, 121.2)	0.2 (0.2, 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.

SHIELD Scientific
compliance comfort protection

Cisco Robles
General Manager