Technical data sheet

DuPont™ Tyvek® IsoClean® , *Model IC 501 B WH MS*

CAT I Option MS SAL

Product Description

DuPont™ Tyvek® IsoClean® sleeve model IC 501 B WH MS. Clean-processed and gamma-sterilized. Bound internal seams. Tunnelled elastication at wrist and bicep. Aseptically folded. White.

Certifications

- PPE Category I

Packaging(Quantity/Box)

100 per box, individually packed in pairs. Subgrouped by 25 in an outer bag. 2 polyethylene liners. Cardboard box.

Cleanroom - Sterilization

- Clean-processed and sterilised by gamma-irradiation to SAL of 10^{-6} (ISO 11137-1)
- Full traceability on all sterilized apparel with certificates of sterility available
- Suitable for use in GMP class A/B (ISO Class 5) clean rooms

Size	Article Number	Length(cm/in)	Wrist opening ø (cm/in)	Upper arm opening (in/cm)	Additional info
00	D15466036	46/18	15/6	25.5/10	One Size

Reference Number: IC 501 B WH MS

Physical Properties

Property	Test Method	Result	EN Class
Colour	N/A	White	N/A
Basis Weight	DIN EN ISO 536	45 g/m^2	N/A
Thickness	DIN EN ISO 534	185 µm	N/A
Abrasion Resistance [7]	EN 530 Method 2	>10 cycles	1 of 6 [1]
Flex Cracking Resistance [7]	EN ISO 7854 Method B	>100000 cycles	6 of 6 [1]
Trapezoidal Tear Resistance (MD)	EN ISO 9073-4	>10 N	1 of 6 [1]
Trapezoidal Tear Resistance (XD)	EN ISO 9073-4	>10 N	1 of 6 [1]
Tensile Strength (MD)	DIN EN ISO 13934-1	>30 N	1 of 6 [1]
Tensile Strength (XD)	DIN EN ISO 13934-1	>30 N	1 of 6 [1]
Puncture Resistance	EN 863	>5 N	1 of 6 [1]
Resistance to Water Penetration	DIN EN 20811	7 kPa	N/A
Surface Resistance at RH 25%, inside [7]	EN 1149-1	2^{10} Ohm	N/A
Exposure to high Temperature	N/A	Melting point ~135 °C	N/A

1 According to EN 14325 **2** According to EN 14126 **3** According to EN 1073-2 **4** According to EN 14116 **12** According to EN 11612 **5** Front Tyvek ® / Back **6** Based on test according to ASTM D-572 **7** See Instructions for Use for further information, limitations and warnings **>** Larger than **<** Smaller than **N/A** Not Applicable **STD DEV** Standard Deviation

Comfort

Property	Test Method	Result	EN Class
Air Permeability (Gurley method)	ISO 5636-5	Yes	N/A
Air Permeability (Gurley method)	ISO 5636-5	4 s	N/A
Water Vapour Resistance, Ret	EN 31092/ISO 11092	6.8 m^2*Pa/W	N/A
Thermal Resistance, Rct	EN 31092/ISO 11092	$10*10^{-3}$ m^2*K/W	N/A
Thermal Resistance, clo value	EN 31092/ISO 11092	0.065 clo	N/A

2 According to EN 14126 **5** Front Tyvek ® / Back **>** Larger than **<** Smaller than **N/A** Not Applicable

Penetration and Repellency

Property	Test Method	Result	EN Class
Resistance to Penetration by Liquids, Sulphuric Acid (30%)	EN ISO 6530	<1 %	3 of 3 [1]
Resistance to Penetration by Liquids, Sodium Hydroxide (10%)	EN ISO 6530	<5 %	2 of 3 [1]
Repellency to Liquids, Sulphuric Acid (30%)	EN ISO 6530	>95 %	3 of 3 [1]
Repellency to Liquids, Sodium Hydroxide (10%)	EN ISO 6530	>90 %	2 of 3 [1]

1 According to EN 14325 **>** Larger than **<** Smaller than

Biological Barrier

Property	Test Method	Result	EN Class
Resistance to Penetration by Blood and Body Fluids using Synthetic Blood	ISO 16603	Pass	3 of 6 [2]
Resistance to Penetration by Blood-borne Pathogens using Bacteriophage Phi-X174	ISO 16604 Procedure C	No classification	No classification [2]
Resistance to Penetration by Contaminated Liquids	EN ISO 22610	Pass	1 of 6 [2]
Resistance to Penetration by Biologically Contaminated Aerosols	ISO/DIS 22611	Pass	1 of 3 [2]
Resistance to Penetration by Contaminated Solid Particles	ISO 22612	Pass	1 of 3 [2]

2 According to EN 14126 **>** Larger than **<** Smaller than

Cleanliness

Property	Test Method	Result	EN Class
Bacterial Filtration Efficiency (3 µm)	ASTM F2101	98.4 % ± 0.9 % STD DEV	N/A
Particle Shedding (Helmke Drum)	IEST-RP-CC003.4.	Category I	N/A

5 Front Tyvek ® / Back **>** Larger than **<** Smaller than **N/A** Not Applicable **STD DEV** Standard Deviation

Important Note

- The intended use for Tyvek® IsoClean Accessories, that are not CE certified or certified as PPE Category I, does not include applications that may cause very serious consequences such as irreversible damage to health or death. The user should make the risk assessment to determine the protection required.

Permeation Data for Tyvek® IsoClean® CS

Hazard Name	Physical State	CAS	BT Act	BT 0.1	BT 1.0	EN	SSPR	MDPR	Cum Time 480	ISO 150
Carboplatin (10mg/ml)	Liquid	441575-94-4	>240	>240	>240	5	<0.001	0.001		
Carmustine (3.3 mg/ml, 10 % Ethanol)	Liquid	154-93-8	<10	<10	>240	5	<0.3	0.001		
Cisplatin (1 mg/ml)	Liquid	15663-27-1	>240	>240	>240	5	<0.001	0.001		
Cyclophosphamide (20 mg/ml)	Liquid	50-18-0	>240	>240	>240	5	<0.008	0.008		
Doxorubicin HCl (2 mg/ml)	Liquid	25136-40-9	>240	>240	>240	5	<0.001	0.001		
Etoposide (Toposar®, Teva) (20 mg/ml, 33.2 % (v/v) Ethanol)	Liquid	33419-42-0	>240	>240	>240	5	<0.01	<0.01		
Fluorouracil, 5- (50 mg/ml)	Liquid	51-21-8	<10	<10	<10		na	0.001		
Gemcitabine (38 mg/ml)	Liquid	95058-81-4	<10	<60	>240	5	<0.4	0.005		
Ifosfamide (50 mg/ml)	Liquid	3778-73-2	>240	>240	>240	5	<0.009	0.009		
Oxaliplatin (5 mg/ml)	Liquid	63121-00-6	<10	<10	<10		na	0.001		
Paclitaxel (Hospira) (6 mg/ml, 49.7 % (v/v) Ethanol)	Liquid	33069-62-4	>240	>240	>240	5	<0.01	<0.01		
Thiotepa (10 mg/ml)	Liquid	52-24-4	<10	<10	<10		na	0.001		

BT Act (Actual) Breakthrough time at MDPR [mins] **BT 0.1** Normalized breakthrough time at 0.1 µg/cm²/min [mins] **BT 1.0** Normalized breakthrough time at 1.0 µg/cm²/min [mins] **EN** Classification according to EN 14325 **SSPR** Steady state permeation rate [µg/cm²/min] **MDPR** Minimum detectable permeation rate [µg/cm²/min] **CUM 480** Cumulative permeation mass after 480 mins [µg/cm²] **Time 150** Time to reach cumulative permeation mass of 150 µg/cm² [mins] **ISO** Classification according to ISO 16602 **CAS** Chemical abstracts service registry number **mins** Minutes **>** Larger than **<** Smaller than **imm** Immediate (< 4 min) **nm** Not tested **sat** Saturated solution **N/A** Not Applicable ***** Based on lowest single value **na** Not attained **8** Actual breakthrough time; normalized breakthrough time is not available

Important Note

The permeation data published have been generated for DuPont by independent accredited testing laboratories according to the test method applicable at that time (EN369, ASTM F739, EN 374-3, EN ISO 6529 (method A and B) or ASTM D6978)
The data is typically the average of three fabrics samples tested.
All chemicals have been tested at an assay of greater than 95 (w/w) % unless otherwise stated.
The tests were performed at room temperature and environmental pressure unless otherwise stated.
A different temperature may have significant influence on the breakthrough time.
Permeation typically increases with temperature.

Cumulative permeation data have been measured or have been calculated based on steady state permeation rate.
Cytostatic drugs testing has been performed at a test temperature of 27°C according to ASTM D6978 or ISO 6529 with the additional requirement of reporting a normalized breakthrough time at 0.01 µg/cm²/min.
Chemical warfare agents (Lewisite, Sarin, Soman, Mustard, Tabun and VX Nerve Agent) have been tested according to MIL-STD-282 at 22°C or according to FINABEL 0.7 at 37°C.
Permeation data for Tyvek® is applicable to white Tyvek® 500/ Tyvek® 600 only and is not applicable for other Tyvek® styles or colours.
Permeation data are usually measured for single chemicals. The permeation characteristics of mixtures can often deviate considerably from the behaviour of the individual chemicals.

Please use the permeation data provided as a part of the risk assessment to assist with the selection of a protective fabric, garment or accessory suitable for your application. Breakthrough time is not the same as safe wear time. Breakthrough times are indicative of the barrier performance, but results can vary between the test methods and laboratories. Breakthrough time alone is insufficient to determine how long a garment may be worn once the garment has been contaminated. Safe user wear time may be longer or shorter than the breakthrough time depending on the permeation behaviour of the substance, the toxicity of the substance, working conditions and the exposure conditions (e.g. temperature, pressure, concentration, physical state).

Latest Update Permeation Data: 30/05/2018

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The information provided herein corresponds to our knowledge on the subject at the date of its publication. This information may be subject to revision as new knowledge and experience becomes available. The data provided fall within the normal range of product properties and relate only to the specific material designated; these data may not be valid for such material used in combination with any other materials or additives or in any process, unless expressly indicated otherwise. The data provided should not be used to establish specification limits or used alone as the basis of design; they are not intended to substitute for any testing you may need to conduct to determine for yourself the suitability of a specific material for your particular purposes. Since DuPont cannot anticipate all variations in actual end-use conditions DuPont makes no warranties and assumes no liability in connection with any use of this information. Nothing in this publication is to be considered as a license to operate under or a recommendation to infringe any patent rights.

For further product information, literature and as well as assistance in locating a local supplier, please visit:

www.safespec.dupont.co.uk

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The footnotes can be found on the SafeSPEC™ website.

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