Technical Data Sheet

DuPont™ Tyvek® IsoClean® , Model IC 501 B WH 00

CAT III PB[6] EN 14126

Tyvek® IsoClean®

DuPont™ Tyvek® IsoClean® sleeve model IC501B00. Not clean-processed and not sterilized. Bound internal seams. Tunnelled elastication at wrist and bicep. White.

Certifications

- Certified according to Regulation (EU) 2016/425
- Partial body chemical protective clothing, Category III, Type PB [6-B]
- EN 14126 (barrier to infective agents)
- Suitable for use in GMP class C/D (ISO Class 6-9) clean rooms

Packaging(Quantity/Box)

100 per box, bulk packed. 2 polyethylene liners. Cardboard box.

Product Size	Article Number	Additional info
00	D15531634	One Size

Full Part Number: IC0501BWH00

PHYSICAL PROPERTIES

Property	Test Method	Typical Result	EN
Abrasion Resistance [7]	EN 530 Method 2	>100 cycles	2/6 [1]
Colour	N/A	White	N/A
Flex Cracking Resistance [7]	EN ISO 7854 Method B	>100000 cycles	6/6 [1]
Puncture Resistance	EN 863	>10 N	2/6 [1]
Tensile Strength (MD)	DIN EN ISO 13934-1	>30 N	1/6 [1]
Tensile Strength (XD)	DIN EN ISO 13934-1	>30 N	1/6 [1]
Trapezoidal Tear Resistance (MD)	EN ISO 9073-4	>10 N	1/6 [1]
Trapezoidal Tear Resistance (XD)	EN ISO 9073-4	>10 N	1/6 [1]

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

GARMENT PERFORMANCE

Property	Test Method	Typical Result	EN
Seam Strength	EN ISO 13935-2	>30 N	1/6 [1]
Type PB 6: Partial Body Protection	EN 13034	Pass	N/A

1 According to EN 14325 **3** According to EN 1073-2 **12** According to EN 11612 **13** According to EN 11611 **5** Front Tyvek ® / Back **6** Based on test according to ASTM D-572 **7** See Instructions for Use for further information, limitations and warnings **11** Based on the average of 10 suits, 3 activities, 3 probes **>** Larger than **<** Smaller than **N/A** Not Applicable ***** Based on lowest single value

PENETRATION AND REPELLENCY

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

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

BIOLOGICAL BARRIER

Property	Test Method	Typical Result	EN
Resistance to Penetration by Biologically Contaminated Aerosols	ISO/DIS 22611	Pass	1/3 [2]
Resistance to Penetration by Blood and Body Fluids using Synthetic Blood	ISO 16603	3,5 kPa	3/6 [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	≤ 15 min	1/6 [2]
Resistance to Penetration by Contaminated Solid Particles	ISO 22612	Pass	1/3 [2]

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

Permeation Data for Tyvek® IsoClean®

Hazard / Chemical Name	Physical State	CAS	BT Act	BT 0.1	BT 1.0	EN	SSPR	MDPR	Cum 480 Time 150 ISO
Acetic acid (30%)	Liquid	64-19-7	imm	imm	imm		13.5	0.001	
Ammonium hydroxide (16%)	Liquid	1336-21-6	imm	imm	imm		20.3	0.005	
Ammonium hydroxide (28% - 30%)	Liquid	1336-21-6	imm	imm	imm		16.7	0.014	
Carboplatin (10 mg/ml)	Liquid	41575-94-4	>240	>240	>240	5	<0.001	0.001	
Carmustine (3.3 mg/ml, 10 % Ethanol)	Liquid	154-93-8	imm	imm	>240	5	<0.3	0.001	
Caustic ammonia (16%)	Liquid	1336-21-6	imm	imm	imm		20.3	0.005	
Caustic ammonia (28% - 30%)	Liquid	1336-21-6	imm	imm	imm		16.7	0.014	
Caustic soda (10%)	Liquid	1310-73-2	>240	>480	>480	6	<0.005	0.005	
Caustic soda (40%)	Liquid	1310-73-2	imm	>30	>240	5	<0.005	0.005	
Caustic soda (50%)	Liquid	1310-73-2	imm	>30	>240	6	0.85	0.01	
Caustic soda (>95%, solid)	Solid	1310-73-2	>480	>480	>480	6	<0.01	0.01	
Cisplatin (1 mg/ml)	Liquid	15663-27-1	>240	>240	>240	5	<0.0002	0.0002	
Cyclo phosphamide (20 mg/ml)	Liquid	50-18-0	>240	>240	>240	5	<0.002	0.002	
Dimethyl sulfate	Liquid	77-78-1	imm	imm	imm		>160	0.02	
Doxorubicin HCl (2 mg/ml)	Liquid	25136-40-9	>240	>240	>240	5	<0.003	0.003	
Ethane 1,2-diol	Liquid	107-21-1	imm	imm	imm		6.6	0.002	
Ethylene glycol	Liquid	107-21-1	imm	imm	imm		6.6	0.002	
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	imm	imm	>30	2	na	0.001	
Formic acid (30%)	Liquid	64-18-6	imm	imm	imm		nm	0.001	
Ganciclovir (3 mg/ml)	Liquid	82410-32-0	>240	>240	>240	5	<0.005	0.005	
Gemcitabine (38 mg/ml)	Liquid	95058-81-4	imm	>60	>240	5	<0.4	0.005	
Glycerine	Liquid	56-81-5	>240	>480	>480	6	0.03	0.01	
Glycerol	Liquid	56-81-5	>240	>480	>480	6	0.03	0.01	
Glycol alcohol	Liquid	107-21-1	imm	imm	imm		6.6	0.002	
Hydrochloric acid (16%)	Liquid	7647-01-0	imm	imm	imm		na	0.05	
Hydrochloric acid (32%)	Liquid	7647-01-0	imm	imm	imm		na	0.05	
Hydrogen peroxide (10%)	Liquid	7722-84-1	>10	>10	>480	6	<0.01	0.01	
Hydrogen peroxide (30%)	Liquid	7722-84-1	imm	imm	imm		>0.11	0.04	

Permeation Data for Tyvek® IsoClean®

Hazard / Chemical Name	Physical State	CAS	BT Act	BT 0.1	BT 1.0	EN	SSPR	MDPR	Cum 480 Time 150 ISO
Ifosfamide (50 mg/ml)	Liquid	3778-73-2	imm	imm	>240	5	<0.5	0.003	
Irinotecan (20 mg/ml)	Liquid	100286-90-6	imm	>240	>240	5	<0.1	0.0028	
Methotrexate (25 mg/ml, 0.1 N NaOH)	Liquid	59-05-2	>240	>240	>240	5	<0.001	0.001	
Mitomycin (0.5 mg/ml)	Liquid	50-07-7	>240	>240	>240	5	<0.0009	0.0009	
Nicotine (9 mg/ml)	Liquid	54-11-5	>480	>480	>480	6	<0.08	0.08	
Nitric acid (10%)	Liquid	7697-37-2	>60	>120	>480	6	na	0.05	
Nitric acid (30%)	Liquid	7697-37-2	imm	imm	imm		4.6	0.001	
Oxaliplatin (5 mg/ml)	Liquid	63121-00-6	imm	imm	imm		na	0.006	
Paclitaxel (Hospira) (6 mg/ml, 49.7 % (v/v) Ethanol)	Liquid	33069-62-4	>240	>240	>240	5	<0.01	<0.01	
Phosphoric acid (50%)	Liquid	7664-38-2	>480	>480	>480	6	<0.05	0.05	
Potassium chromate (sat)	Liquid	7789-00-6	>480	>480	>480	6	<0.005	0.005	
Potassium hydroxide (40%)	Liquid	1310-58-3	imm	imm	>30	2	0.7	0.001	
Propane -1,2,3-triol	Liquid	56-81-5	>240	>480	>480	6	0.03	0.01	
Sodium acetate (sat)	Liquid	127-09-3	imm	>480	>480	6	<0.1	0.05	
Sodium chloride (9 g/l)	Liquid	7647-14-5	>240	>240	>240	5	<0.02	0.02	
Sodium hydroxide (10%)	Liquid	1310-73-2	>240	>480	>480	6	<0.005	0.005	
Sodium hydroxide (40%)	Liquid	1310-73-2	imm	>30	>240	5	<0.005	0.005	
Sodium hydroxide (50%)	Liquid	1310-73-2	imm	>30	>240	6	0.85	0.01	
Sodium hydroxide (>95%, solid)	Solid	1310-73-2	>480	>480	>480	6	<0.01	0.01	
Sodium hypochlorite (10-15 % active chlorine)	Liquid	7681-52-9	>240	>240	>480	6	<0.6	0.05	
Sodium hypochlorite (5.25-6%)	Liquid	7681-52-9	>480	>480	>480	6	<0.025	0.025	
Sulfuric acid (18%)	Liquid	7664-93-9	>240	>240	>480	6	<0.05	0.05	
Sulfuric acid (30%)	Liquid	7664-93-9	>10	>240	>240	5	<0.05	0.05	
Sulfuric acid (50%)	Liquid	7664-93-9	imm	>30	>60	3	38	0.01	
Sulfuric acid dimethyl ester	Liquid	77-78-1	imm	imm	imm		>160	0.02	
Thiotepa (10 mg/ml)	Liquid	52-24-4	imm	imm	imm		na	0.001	
Vincristine sulfate (1 mg/ml)	Liquid	2068-78-2	>240	>240	>240	6	<0.001	0.001	
Vinorelbine (0.1 mg/ml)	Liquid	71486-22-1	>240	>240	>240	6	<0.0209	0.00209	

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 (EN ISO 6529 (method A and B), ASTM F739, ASTM F1383, ASTM D6978, EN369, EN 374-3)
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 between 20 °C and 27 °C and at 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 minimum detectable 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 and 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.

The permeation data for gloves published have been generated according to ASTM F739 and to ASTM F1383.
The degradation data for gloves published have been generated based on a gravimetric method.
This degradation testing exposes one side of the glove material to the test chemical for four hours. The percent weight change after exposure is measured at four time intervals: 5, 30, 60 and 240 minutes.

Degradation Ratings:

- E: EXCELLENT (0-10% Weight Change)
- G: GOOD (11-20% Weight Change)
- F: FAIR (21-30% Weight Change)
- P: POOR (31-50% Weight Change)
- NR: NOT RECOMMENDED (Above 50% Weight Change)
- NT: NOT TESTED

Degradation is the physical change in a material after chemical exposure. Typical observable effects may be swelling, wrinkling, deterioration, or delamination. Strength loss may also occur.

Please use the permeation data provided as a part of the risk assessment to assist with the selection of a protective fabric, garment, glove 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 orshorter 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: 5/5/2020

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- 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.

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

www.safespec.dupont.co.uk

The footnotes can be found on the SafeSPEC™ website.

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