Technical Data Sheet

Tyvek® IsoClean®, Model IC 729 S WH MS

CAT I Option MS SAL



Tyvek® IsoClean®

DuPont™ Tyvek® IsoClean® bouffant model IC 729 S WH MS. Clean-processed and gamma-sterilized. Elastic headband. White.

Certifications

- 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
- PPE Category I

Packaging(Quantity/Box)

250 per box, individually packed. Subgrouped by 50 in an outer bag. 2 polyethylene liners. Cardboard box.

Full Part Number: IC0729SWHMS

PHYSICAL PROPERTIES

Property	Test Method	Typical Result	EN
Abrasion Resistance [7]	EN 530 Method 2	>10 cycles	1/6 [1]
Basis Weight	DIN EN ISO 536	45 g/m^2	N/A
Colour	N/A (598)	White	N/A
Exposure to high Temperature	N/A (598)	Melting point ~135 °C	N/A
Flex Cracking Resistance [7]	EN ISO 7854 Method B	>100000 cycles	6/6 [1]
Puncture Resistance	EN 863	>5 N	1/6 [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
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]
Thickness	DIN EN ISO 534	185 µm	N/A
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

COMFORT

Property	Test Method	Typical Result	EN
Air Permeability (Gurley method)	ISO 5636-5	Yes	N/A
Air Permeability (Gurley method)	ISO 5636-5	4 s	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
Water Vapour Resistance, Ret	EN 31092/ISO 11092	6.8 m^2*Pa/W	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	Typical Result	EN
Repellency to Liquids, Sodium Hydroxide (10%)	EN ISO 6530	>90 %	2/3 [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	<5 %	2/3 [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

CLEANLINESS

Property	Test Method	Typical Result	EN

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

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
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			
Cisplatin (1 mg/ml)	Liquid	15663-27-1	>240	>240	>240	5	<0.001	0.001			
Cyclo phosphamide (20 mg/ml)	Liquid	50-18-0	imm	>10	>240	5	na	0.003			
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	imm	imm	imm		na	0.001			
Gemcitabine (38 mg/ml)	Liquid	95058-81-4	imm	>60	>240	5	<0.4	0.005			
Ifosfamide (50 mg/ml)	Liquid	3778-73-2	imm	imm	>60	3	na	0.003			
Oxaliplatin (5 mg/ml)	Liquid	63121-00-6	imm	imm	imm		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	imm	imm	imm		na	0.001			

BTAct (Actual) Breakthrough time at MDPR [mins] BT0.1 Normalized breakthrough time at 0.1 µg/cm²/min [mins] BT1.0 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] CUM480 Cumulative permeation mass after 480 mins [µg/cm²] Time150 Time to reach cumulative permeation mass of 150 µg/cm² [mins] ISO Classification according to ISO 16602 CAS Chemical abstracts service registry number min Minute > Larger than < Smaller than imm Immediate (< 10 min) nm Not tested sat Saturated solution N/A Not Applicable na Not attained GPR grade General purpose reagent grade * Based on lowest single value 8 Actual breakthrough time; normalized breakthrough time is not available DOT5 Degradation after 5 min DOT30 Degradation after 30 min DOT60 Degradation after 60 min DOT240 Degradation after 240 min BT1383 Normalized breakthrough time at 0.1 µg/cm²/min [mins] acc. ASTM F1383

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.