Technical Data Sheet

Tyvek® IsoClean®, Model 9820 MS

CAT I

Tyvek® IsoClean®

DuPont™ Tyvek® IsoClean® hood and mask model IC 9820 WH MS. Clean-processed and gamma-sterilized. HOOD: Bound seams. Bound head opening. Ties with loops. White. MASK: Pleated Polyethylene outer. 17,5 cm Sterile. Blue.

Certifications

- Sterilized 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 C/D (ISO Class 6-9) clean rooms withor without Bioburden Control Areas
- PPE Category I

Packaging(Quantity/Box)

100 per box, individually packed (1 set per bag). Subgrouped by 20 in an outer bag. 2 polyethylene liners. Cardboard box.

Full Part Number: 9820 MS

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

CLEANLINESS			
Property	Test Method	Typical Result	EN
Bacterial Filtration Efficiency (3 µm)	ASTM F2101	98.9 % ± 1.2 % 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

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

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.

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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.