

SINCE 1925

# KEYSTONE

SAFETY ↔ CLEANROOM PRODUCTS

## PURECLEAN™ SELF-SEALING 1421B TYVEK® AUTOCLAVE BAG WITH CLEAR FILM SIDE AND STEAM INDICATOR

PureClean™ Self-Sealing Autoclave Bags are made from a transparent film and 1421B DuPont™ Tyvek®, which is a new grade of uncoated, untreated, flexible Tyvek® material specifically designed for pharmaceutical use in steam sterilization applications.



- Uncoated Tyvek® eliminates potential of residue deposits on equipment, post sterilization
- Clear Side enables visual confirmation of dryness for sterilized parts and equipment, which is required by EU GMP Annex 1
- Convenient Self-Seal Closure eliminates the need for autoclave tape or the validation and use of a heat sealer
- Fast and consistent for equipment preparation area
- Resists tearing and punctures
- Superior microbial barrier
- Manufactured and packaged in a certified ISO 6 cleanroom
- Made in the USA
- Certificates of Conformance sent with shipment

### MATERIAL SPECIFICATIONS:

Property	Comparable standard test method	Units	Nominal value (range) Tyvek® 1421B
<b>Preliminary product specifications (English units)</b>			
Basis weight	ASTM D3776 <sup>1</sup>	oz/yd <sup>2</sup>	1.22 [1.16–1.26]
Delamination	ASTMD2724 <sup>2</sup>	lb <sub>f</sub>	0.08 [>0.03]
Gurley Hill porosity	TAPPI T460 <sup>3</sup>	sec/100 cc	20 [8–36]
<b>Preliminary product specifications (metric units)</b>			
Basis weight	ASTM D3776 <sup>1</sup>	g/m <sup>2</sup>	41 [39–43]
Delamination	ASTMD2724 <sup>2</sup>	N	0.36 [>0.13]
Gurley Hill porosity	TAPPI T460 <sup>3</sup>	sec/100 cc	20 [8–36]

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**SELF-SEALING 1421B TYVEK® AUTOCLAVE BAG WITH CLEAR FILM SIDE AND STEAM INDICATOR**

Property (Continued)	Comparable standard test method	Units	Typical value Tyvek® 1421B
<b>Preliminary miscellaneous properties (English units)</b>			
Thickness	EN ISO 534 <sup>1</sup>	mils	6 (0.15mm)
Tensile strength, MD	EN ISO 1924-2 <sup>2</sup>	lb /in	7.6
Tensile strength, CD	EN ISO 1924-2 <sup>2</sup>	lb /in	6.4
Elmendorf tear, MD	ASTM D1424	lb <sub>f</sub>	2.4
Elmendorf tear, CD	ASTM D1424	lb <sub>f</sub>	1.9
Hydrostatic head	AATCC TM 127 <sup>3</sup>	in H <sub>2</sub> O	44
Elongation, MD	EN ISO 1924-2 <sup>2</sup>	%	10
Elongation, CD	EN ISO 1924-2 <sup>2</sup>	%	15
Puncture resistance	EN 863 <sup>4</sup>	lb <sub>f</sub>	2.7
Mullen burst	ISO 2758	psi	53
Bendsten air permeability	ISO 5636-3 <sup>5</sup>	mL/min	741
Microbial barrier	ASTM F1608	LRV	~4

MD = machine direction; CD = cross direction

1. Surface 2 cm<sup>2</sup>, pressure 50 kPa.

2. Modified for speed, sample width 2.54 cm (1 inch).

3. Rate of use: 60 cm H<sub>2</sub>O/min.

4. Modified for conditioning.

5. Electronic device.

Property	Comparable standard test method	Units	Typical value Tyvek® 1421B
<b>Preliminary miscellaneous properties (metric units)</b>			
Thickness	EN ISO 534 <sup>1</sup>	µm	152
Tensile strength, MD	EN ISO 1924-2 <sup>2</sup>	N	34
Tensile strength, CD	EN ISO 1924-2 <sup>2</sup>	N	28
Elmendorf tear, MD	ASTMD1424	N	10.6
Elmendorf tear, CD	ASTMD1424	N	8.5
Hydrostatic head	AATCC TM 127 <sup>3</sup>	cm H <sub>2</sub> O	112
Elongation, MD	EN ISO 1924-2 <sup>2</sup>	%	10
Elongation, CD	EN ISO 1924-2 <sup>2</sup>	%	15
Puncture resistance	EN 863 <sup>4</sup>	N	12
Mullen burst	ISO 2758	kPa	365
Bendsten air permeability	ISO 5636-3 <sup>5</sup>	mL/min	741
Microbial barrier	ASTM F1608	LRV	~4

MD = machine direction; CD = cross direction

1. Surface 2 cm<sup>2</sup>, pressure 50 kPa.

2. Modified for speed, sample width 2.54 cm (1 inch).

3. Rate of use: 60 cm H<sub>2</sub>O/min.

4. Modified for conditioning.

5. Electronic device.

**SELF-SEALING 1421B TYVEK® AUTOCLAVE BAG WITH CLEAR FILM SIDE AND STEAM INDICATOR**



KEYSTONE PART NUMBER	DIMENSIONS	KEYSTONE PART NUMBER	DIMENSIONS
6STKRP0205SS	5.08 cm x 12.7 cm	6STKRP1830SS	45.72 cm X 76.2 cm
6STKRP0404SS	10.16 cm x 10.16 cm	6STKRP2020SS	50.8 cm x 50.8 cm
6STKRP0409SS	10.16 cm x 22.86 cm	6STKRP2024SS	50.8 cm x 60.96 cm
6STKRP0416SS	10.16 cm x 40.64 cm	6STKRP2030SS	50.8 cm x 76.2 cm
6STKRP0820SS	20.32 cm x 50.8 cm	6STKRP2040SS	50.8 cm x 101.6 cm
6STKRP09-512SS	24.13 cm x 30.48 cm	6STKRP2224SS	55.88 cm x 60.96 cm
6STKRP1015SS	25.4 cm x 38.1 cm	6STKRP2424SS	60.96 cm x 60.96 cm
6STKRP1020SS	25.4 cm x 50.8 cm	6STKRP2436SS	60.96 cm x 91.44 cm
6STKRP1212SS	30.48 cm x 30.48 cm	6STKRP2448SS	60.96 cm x 121.92 cm
6STKRP1216SS	30.48 cm x 40.64 cm	6STKRP2844SS	71.12 cm x 111.76 cm
6STKRP1218SS	30.48 cm x 45.72 cm	6STKRP3036SS	76.2 cm x 91.44 cm
6STKRP1234SS	30.48 cm x 86.36 cm	6STKRP3636SS	91.44 cm x 91.44 cm
6STKRP1240SS	30.48 cm x 101.6 cm	6STKRP3648SS	91.44 cm X 121.92 cm
6STKRP1246SS	30.48 cm x 116.84 cm	6STKRP3660SS	91.44 cm x 152.4 cm
6STKRP1248SS	30.48 cm x 121.92 cm	6STKRP4848SS	121.92 cm x 121.92 cm
6STKRP1624SS	40.64 cm x 60.96 cm	6STKRP4860SS	121.92 cm x 152.4 cm