

Product Information ISO Class 5 – 8 Cleanroom Class 100 - 100,000 EU Grade A/B/C/D USP <797>

# Sterile SatPax<sup>®</sup> 670

# Sterile Pre-wetted 55% Cellulose / 45% Polyester Nonwoven Cleanroom Wiper

Sterile SatPax<sup>®</sup> 670 combines Durx<sup>®</sup> 670 nonwoven wipers composed of a hydroentangled nonwoven blend of 55% cellulose and 45% polyester with a high saturation level of 70% IPA and 30% DI water. This pre-wetted format provides

a cost effective and easy to use solution versus tradition- irradiated sterile to a 10<sup>-6</sup> Sterility Assurance Level al bulk handling of solvents, maintenance of squirt bottles and inconsistent wetting and cleaning associated with wetting a dry wiper. Each package is then gamma

making the product ideal for cleaning critical sterile processing environments.



### **Other Sterile Pre-wetted wipers**

- Sterile SatPax® 1000
- Sterile SatPax®1200
- Sterile SatPax®-HA

#### **Key Attributes**

- 55% cellulose / 45% polyester hydroentangled nonwoven blend
- No chemical binders in base material
- Pre-wetted with consistent 70% IPA/ 30% DI Water to a high saturation level
- Re-sealable solvent resistant packaging
- Wipers in c-folded configuration for single withdrawal
- Gamma irradiated and sterile validated to a 10<sup>-6</sup> Sterility Assurance Level per AAMI guidelines
- Certificate of Sterility available to down load on the web by lot number 24/7. Details: Expiration Date, Radiation Dosage, Lot Information, Meets cGMP requirements for traceability

#### **Benefits**

.

- Low extractables and fiber and particle counts
- Smooth and durable with good wet strength
- Reduces alcohol usage and preparation / handling costs
- Reduces VOC emissions
- Increases cleaning efficiency
- Increases cleaning protocol consistency

#### **Environmental**

- Reduces VOC (Volatile Organic Compound) emissions
- 55% cellulose fiber content is biodegradable
- Complies with RoHS
- Registered under REACH

#### Applications

- Designed for use in ISO Class 5 and higher sterile cleanroom environments and USP <797> applications
- Designed for use in wet cleaning of critical surfaces where control of flammable solvents and flammable solvent concentrations is required
- Final cleaning of surfaces or products prior to manufacturing or packaging
- High saturation level is ideal for removing cleaning and disinfecting residues in sterile environments
- Meets AMS 3819C requirements, Class2, Grade A, Form 2

#### Saturation Levels

The amount of solution contained in each wiper can be varied according to customer requirements. Higher saturation levels apply more solution to the surface during cleaning.

#### Validated Sterile

ANSI/AAMI/ISO procedures have been followed for verification of irradiation dose with audits being performed to monitor bioburden levels and dose. The Sterility Assurance Level (SAL) or the probability of a viable organism being present on a product unit after sterilization is a SAL of 10<sup>-6</sup> (which is the chance of 1 non-sterile unit in 1,000,000).

www.berkshire.eu.com	Americas	Tel 1 413 528 2602	Fax 1 413 528 2614	info@berkshire.com
Contact: Tel 44 (0) 870 757 2877	Europe	Tel 44 (0) 870 757 2877	Fax 44 (0) 870 757 2878	enquiries@berkshire.uk.com
enquiries@berkshire.uk.com	SE Asia	Tel 65 6252 4313	Fax 65 6252 4312	enquiries@berkshire.com.sg
	Japan	Tel 81 3 5827 2380	Fax 81 3 5827 2382	master@berkshire.co.jp
DU 4004 00 0004				



# **Technical Data (In Dry State)**

Attribute		Units	Value	Test Method
Basis Weight		g/m <sup>2</sup>	68.0	TAPPI T-410
Caliper		μm	264	TAPPI T-411
Fibers	≥100µm	fibers/cm <sup>2</sup>	160	IEST-RP.CC004.3, Sec 6.1.3 / Sec 6.2.2
Particles	≥0.5µm	x10 <sup>3</sup> /cm <sup>2</sup>	10	IEST-RP.CC004.3, Sec 6.1.3 / Sec 6.2.1
Sorbency	Capacity	mL/m <sup>2</sup>	320	IEST-RP.CC004.3, Sec 8.1 modified / Sec 8.2 modified
	Efficiency	mL/g	4.7	
	Rate	seconds	2	
Non-Volatile Residue	DI Water	g/m <sup>2</sup>	0.028	IEST-RP.CC004.3, Sec 7.1.2
	IPA	g/m <sup>2</sup>	0.0038	
Ions	Na⁺	ppm	62	IEST-RP.CC004.3, Sec 7.2.2
	K+	ppm	5.9	
	Ca++	ppm	22	
	Mg <sup>++</sup>	ppm	5.0	
	CI-	ppm	31	

#### Notes:

otes:

Technical data represented in this table are typical values at the time of publication. These should not be used as product specifications.

Due to differences in test methods applied and equipment utilized by different wiper manufacturers, valid product comparisons may only be obtained through side-by-side testing in the same test facility, under similar conditions
Third party testing can be performed upon request

## Order Information:

Product	Number	Size	Shts/pk	Pks/cs	IPA/DI	Saturation	VOC % by Weight	Style
Sterile SatPax <sup>®</sup> 670	SSP67000124	9x9" (23x23cm)	30	24	70/30	60%	44%	C-fold



# www.berkshire.eu.com

Contact: Tel 44 (0) 870 757 2877 / enquiries@berkshire.uk.com BIL\_1204\_09-2021