

**Product Information** 

ISO Class 5 - 8

Cleanroom Class 100 – 100,000 EU Grade A/B/C/D USP <797> <800>, Annex 1

# Sterile SatPax® 670

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



Sterile SatPax® 670 combines Durx® 670 nonwoven wipers composed of a hydroentangled nonwoven blend of 55% cellulose and 45% polyester with a high saturation level of 70% USP Grade IPA and 30% DI water. This pre-wetted format provides a cost-effective and easy-to-use solution versus traditional bulk handling of solvents, maintenance of squirt bottles, and inconsistent wetting and cleaning associated with wetting a dry wiper. Each package is then gamma-irradiated sterile to a 10<sup>-6</sup> Sterility Assurance Level, making the product ideal for cleaning critical sterile processing environments.

Berkshire's SatPax® 70/30 IPA biocidal product range is authorised under the EU Biocidal Product Regulation (EU) 528/2012 for sale throughout the EU and EEA. The products in the range are efficacious against bacteria and yeast, with a contact time of 1 min.



## Other Sterile Pre-wetted wipers in the BPR range

- Sterile SatPax® 1000
- Sterile SatPax® 550

#### **Key Attributes**

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

#### **Benefits**

- Low extractables and fibre 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
- · Lot traceability

### **Applications**

- Designed for use in ISO Class 5 and higher sterile cleanroom environments and USP <797> <800> and Annex 1 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

#### 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.uk.com

Contact: Tel + 44 1953 562800 enquiries@berkshire.uk.com

America	Tel 1 413 528 2602	info@berkshire.com
Europe	Tel + 44 1953 562800	enquiries@berkshire.uk.com
SE Asia	Tel 65 6252 4313	enquiries@berkshire.com.sg
Japan	Tel 81 3 4530 9883	master@berkshire.co.jp



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

Attribute		Units	Value	Test Method			
Basis Weight		g/m²	68.0	TAPPI T-410			
Caliper		μm	264				
Fibres	<u>≥</u> 100µm	fibres/cm <sup>2</sup>	160	IEST-RP-CC004.4 Sec 7.1.3 /Sec 7.2.2 modified			
Particles	<u>&gt;</u> 0.5µm	x10³/cm²	10	IEST-RP-CC004.4 Sec 7.1.3 /Sec 7.2.1 modified			
Sorbency	Capacity	mL/m²	320	IEST-RP-CC004.4 Sec 9.1 /Sec 9.2 modified			
	Efficiency	mL/g	4.7				
	Rate	seconds	2				
Non-Volatile Residue	DI Water	g/m²	0.028	IEST-RP-CC004.4 Sec 8.1.2			
	IPA	g/m²	0.0038				
Ions	Na <sup>+</sup>	ppm	62	IEST-RP-CC004.4 Sec 8.2.2			
	K <sup>+</sup>	ppm	5.9				
	Ca <sup>++</sup>	ppm	22				
	Mg <sup>++</sup>	ppm	5.0				
	CI-	ppm	31				

## **Efficacy Data**

Microorganism	Log Reduction (EN16615)
Staphylococ cus aureus	>6.07
Pseudomonas aeruginosa	>5.30
Enterococcus hirae	5.56
Candida albic ans	>4.32

Berkshire's SatPax® 70/30 IPA biocidal product range is authorised under the EU Biocidal Product Regulation (EU) 528/2012 for sale throughout the EU and EEA. The products in the range are efficacious against bacteria and yeast, with a contact time of 1 min.

### Notes:

- 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 utilised by different wiper manufacturers, valid product comparisons may only be obtained through side-by-side testing in the same test facility, under similar conditions

#### **Order Information:**

Product	Number	Size	Shts/pk	Pks/cs	IPA/DI Water	Saturation	VOC % by Weight	Style
Sterile SatPax® 670	SSP670124BPR	9x9" (23x23cm)	30	24	70/30	60%	44	C-fold

## **Other Berkshire products**



Wipers



**Glove Liners** 



**Mop Systems** 



**Documentation Systems** 



**Face Masks** 



Swabs