

# USP 797 & 800 Compliance Specialists

Everything you need to achieve and maintain a compliant cleanroom environment

# Sterile SatPax<sup>®</sup> 670

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

 $\begin{array}{l} \mbox{Product Information} \\ \mbox{ISO Class 5-8} \\ \mbox{Cleanroom Class 100-100,000} \\ \mbox{EU Grade C/D} \\ \mbox{USP <797>} \end{array}$ 

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 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 10-6 Sterility Assurance Level making the product ideal for cleaning critical sterile processing environments.



## Other Sterile Pre-wetted wipers

- Sterile SatPax<sup>®</sup> 1000
- Sterile SatPax<sup>®</sup>1200
- Sterile SatPax<sup>®</sup> HA
- Sterile SatPax<sup>®</sup> MicroSeal<sup>®</sup> WFI

#### 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 with each case and available on the web by lot number 24/7. Details: Expiration Date, Ra-diation Dosage, Lot Information, Meets cGMP requirements for traceability

## Benefits

Low extractables and fiber and particle counts Smooth and durable with good wet strength Passes LAL test for endotoxins <20 EU/device 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 2002/05 and pre-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

# 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 quarterly 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  $10^{-6}$  (which is the chance of 1 non-sterile unit in 1,000,000).







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## Technical Data (In Dry State)

Attribute		Units	Value	Test Method		
Basis Weight		g/m <sup>2</sup>	68.5	TAPPI T-410		
Caliper		μm	251	TAPPI T-411		
Fibers	<u>&gt;</u> 100µm	fibers/cm <sup>2</sup>	110	IEST-RP.CC004.3, Sec 6.1.3 / Sec 6.2.2		
Particles	<u>&gt;</u> 0.5µm	x10 <sup>3</sup> /cm <sup>2</sup>	20	IEST-RP.CC004.3, Sec 6.1.3 / Sec 6.2.2		
Sorbency	Capacity	mL/m²	301	IEST-RP.CC004.3, Sec 8.1 modified / Sec 8.2 modified		
	Efficiency	mL/g	4.4			
	Rate	seconds	3			
Non-Volatile Residue	DI Water	g/m <sup>2</sup>	0.034	IEST-RP.CC004.3, Sec 7.1.2		
	IPA	g/m <sup>2</sup>	0.0040			
lons	Na <sup>+</sup>	ppm	18	IEST-RP.CC004.3, Sec 7.2.2		
	K+	ppm	0.84			
	Ca <sup>++</sup>	ppm	0.85			
	Mg <sup>++</sup>	ppm	0.44			
	CI	ppm	7.5			

#### Notes:

- All values are statistical averages
- 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	Satura-	VOC % by	Style
Sterile SatPax <sup>®</sup> 670	SSP670.001.24	9x9" (23x23cm)	30	24	70/30	60%	45%	C-fold

