

Product Information ISO Class 3 — 5 Cleanroom Class 1 – 100 EU Grade A/B/C/D

# Sterile SatPax® HA

Sterile Pre-wetted Sealed Edge Cleanroom Laundered 100% Polyester Knit Wiper

Sterile SatPax<sup>®</sup> HA combines ValuSeal<sup>®</sup> HA ultrasonically sealed edge cleanroom laundered wipers composed of 100% continuous filament polyester knit fabric 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<sup>-6</sup> Sterility Assurance Level making the product ideal for cleaning critical sterile processing environments.



## Other Sterile Pre-wetted wipers

- Sterile SatPax<sup>®</sup> 670
- Sterile SatPax<sup>®</sup> 1000
- Sterile SatPax<sup>®</sup> 1200

## **Key Attributes**

- 100% continuous filament polyester knit
- Ultrasonically sealed edge for reduced fiber contamination
- Laundered and packaged in Berkshire's ISO Class 4 cleanroom
- Pre-wetted with consistent 70% IPA/ 30% DI Water to a high saturation level
- Re-sealable solvent resistant packaging
- Wipers in j-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

- Critically low fibers, particles, ions and extractables combined with high abrasion resistance
- Passes LAL test for endotoxins <20 EU/device</li>
- Reduces alcohol usage and preparation / handling costs
- Reduces VOC emissions
- Increases cleaning efficiency
- Increases cleaning protocol consistency

## Environmental

- Reduces VOC (Volatile Organic Compound) emissions
- Lightweight material design can reduce waste disposal pounds compared to traditional heavier weight products
- Complies with RoHS
- Registered under REACH

## Applications

- Designed for use in ISO Class 3 and higher sterile cleanroom environments
- 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<sup>-6</sup> (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/m²	136	TAPPI T-410
Caliper		μm	435	TAPPI T-411
Fibers	<u>&gt;</u> 100µm	fibers/cm <sup>2</sup>	0.080	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>	0.31	IEST-RP-CC004.3, Sec 6.1.3 / Sec 6.2.1
Sorbency	Capacity	mL/m²	567	IEST-RP-CC004.3, Sec 8.1 modified / Sec 8.2 modified
	Efficiency	mL/g	4.2	
	Rate	seconds	1	
Non-Volatile Residue	DI Water	g/m²	0.0042	IEST-RP-CC004.3, Sec 7.1.2
	IPA	g/m²	0.0092	
Ions	Na <sup>+</sup>	ppm	0.41	IEST-RP-CC004.3, Sec 7.2.2
	K <sup>+</sup>	ppm	0.048	
	Ca++	ppm	0.035	
	Mg <sup>++</sup>	ppm	0.0085	
	CI-	ppm	0.21	

#### 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 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> HA	SSPHA.001.12	9x9" (23x23cm)	30	12	70/30	60%	42%	J-fold



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