

**Product Information** 

ISO Class 3 - 5

Cleanroom Class 1 — 100 EU Grade B/C/D

# Sterile SatPax® MicroSeal®-VP Ethanol

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

Sterile SatPax® MicroSeal® VP is an ultrasonically sealed edge cleanroom laundered wiper recommended for ISO Class 3 and above environments composed of 100% continuous filament polyester knit fabric. The wiper is pre-wetted with 70% Ethanol. Each package is gamma irradiated sterile to a 10° Sterility Assurance Level. This combination of properties provides Sterile SatPax® MicroSeal® VP with the highest level of cleanliness, abrasion resistance and chemical compatibility required for cleaning critical sterile processing environments. The Pre-wetted format provides a cost effective and easy to use solution versus traditional bulk handling of solvents and maintenance of squirt bottles



## **Key Attributes**

- 100% continuous filament polyester knit
- Ultrasonically sealed edge for reduced fiber contamination
- Laundered and packaged in Berkshire's ISO Class 4 cleanroom with Lot Number on each pack
- Gamma irradiated and sterile validated to a 10<sup>-6</sup> Sterility Assurance Level per AAMI guidelines
- Pre-wetted with 70% Ethanol
- · Peal and reseal pouches allow for single wiper use and prevent evaporation
- Triple bagged for easy entry into sterile environments
- Certificate of Sterility with each case. Details: Date of Manufacture, Expiration Date, Radiation Dosage, Lot Information, Meets cGMP requirements for traceability

#### Benefits

- · Critically low particles, fibers, ions and extractables
- High abrasion resistance
- High Absorbency
- · Increases cleaning protocol consistency
- · Light weight, high absorbency material design reduces actual cost in use compared to heavier weight products

#### **Environmental**

- Light weight, high absorbency design reduces landfill waste impact when compared to more traditional heavier weight designs
- Reduces VOC (Volatile Organic Compound) emissions

## **Applications**

- Designed for use in ISO Class 3 and higher sterile environments where microbial exclusion is demanded
- Designed for cleaning sterile surfaces and equipment during aseptic processing and USP <797> applications
- · Excellent for cleaning sterile laminar air flow units, barrier isolators and bio-containment units

#### **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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Sterile SatPax® 670 Sterile SatPax® 1000

Sterile SatPax® MicroSeal® WFL



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

Attribute		Units	Value	Test Method
<b>Basis Weight</b>		g/m²	130	TAPPI T-410
Caliper		μm	442	TAPPI T-411
Fibers	≥100µm	fibers/cm <sup>2</sup>	0.012	IEST-RP-CC004.4 Sec 7.1.3/Sec 7.2.2 modified
Particles	≥0.5µm	x10³/cm²	0.31	IEST-RP-CC004.4 Sec 7.1.3/Sec 7.2.1 modified
Sorbency	Capacity	mL/m²	448	IEST-RP-CC004.4 Sec 9.1 / Sec 9.2 modified
	Efficiency	mL/g	3.4	
	Rate	seconds	1	
Non-Volatile Residue	DI Water	g/m²	0.0019	IEST-RP-CC004.4 Sec 8.1.2
	IPA	g/m²	0.0054	
Ions	Na <sup>+</sup>	ppm	0.17	IEST-RP-CC004.4 Sec 8.2.2
	K <sup>+</sup>	ppm	0.024	
	Ca <sup>++</sup>	ppm	0.053	
	Mg <sup>++</sup>	ppm	0.011	
	CI-	ppm	0.032	

#### Notes:

- Technical data represented in this table are typical value 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	Ethanol/DI	Saturation	VOC % by Weight	Style
Sterile SatPax® MSVP	SSPVP001E12	9x9"(23x23cm)	30	12	70/30	60%	43.2%	J-Fold

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