

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

# Sterile SatPax<sup>®</sup> MicroSeal<sup>®</sup>-VP

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

Sterile SatPax<sup>®</sup> MicroSeal<sup>®</sup>-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% USP Grade IPA. Each package is gamma irradiated sterile to a 10<sup>6</sup> Sterility Assurance Level. This combination of properties provides Sterile SatPax<sup>®</sup> MicroSeal<sup>®</sup>-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 bulk handling of solvents and maintenance of squirt traditional bottles.

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

- Sterile SatPax<sup>®</sup> 670
- Sterile SatPax<sup>®</sup> 1000
- Sterile SatPax<sup>®</sup> MicroSeal<sup>®</sup> WFI

## **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 validated sterile to a 10<sup>-6</sup> Sterility Assurance Level per AAMI guidelines
- Pre-wetted with 70% USP Grade IPA
- · Peal and reseal pouches allow for single wiper use and prevent evaporation
- Double wrapped 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

Registered under REACH

# 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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# Technical Data (In Dry State):

Attribute		Units	Value	Test Method	
Basis Weight		g/m²	130	TAPPI T-410	
Caliper		μm	442	TAPPI T-411	
Fibers	≥100µm	fibers/cm <sup>2</sup>	0.12	IEST-RP-CC004.4 Sec 7.1.3/Sec 7.2.2 modified	
Particles	≥ <b>0.5</b> µm	x10 <sup>3</sup> /cm <sup>2</sup>	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+	ppm	0.024		
	Ca++	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	IPA/DI	Saturation	VOC % by Weight	Style
Sterile SatPax® MSVP	SSPVP00124	9x9"(23x23cm)	30	24	70/30	47%	39.5%	J-Fold
Sterile SatPax® MSVP	SSPVPR00124	9x9"(23x23cm)	30	24	70/30	60%	43.2%	J-Fold



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