

Product Information

ISO Class 3 - 5

Cleanroom Class 1 – 100 EU Grade A/B/C/D

Sterile SatPax® MicroSeal®-VP

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% USP Grade IPA. Each package is gamma irradiated sterile to a 10⁻⁶ 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 bulk handling of solvents and maintenance of squirt traditional bottles.



Other Sterile Pre-wetted wipers

- Sterile SatPax® 670
- Sterile SatPax® 1000
- Sterile SatPax® MicroSeal® 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 10⁻⁶ 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 10⁻⁶ (which is the chance of 1 non-sterile unit in 1,000,000).



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 ²	0.12	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 ⁺	ppm	0.17	IEST-RP-CC004.4 Sec 8.2.2		
	K ⁺	ppm	0.024			
	Ca ⁺⁺	ppm	0.053			
	Mg ⁺⁺	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

Other Berkshire products

For information on our other products, please click on the relevant text.



Wipers



Mop Systems



Face Masks



Glove Liners



Documentation Systems



<u>Swabs</u>