Berkshire
ENGINEERED CLEAN

Product Information
ISO Class 3 – 5
Cleanroom Class 1 – 100
EU Grade A/B/C/D
USP <797> <800>, Annex 1

Sterile SatPax® MicroSeal®-VP

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

BPR • AUTHORISED • BIOCIDAL PRODUCTS REGULATION

Sterile SatPax® MicroSeal® - VP is an ultrasonically sealed edge cleanroom-laundered wiper recommended for ISO Class 3 and above environments, made of 100% continuous filament polyester knit fabric. The wiper is pre-wetted with 70% USP Grade IPA and 30% DI Water. 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 offers a cost-effective and easy-to-use solution compared to the bulk handling of solvents and the maintenance of traditional squirt bottles.

Berkshire's SatPax® 70/30 IPA biocidal product range is authorised under the EU Biocidal Product Regulation (EU) 528/2012 for sale throughout the EU and EEA.
The products in the range are efficacious against bacteria and yeast, with a contact time of 1 min.



Key Attributes

- 100% continuous filament polyester knit
- Ultrasonically sealed edge for reduced fibre contamination
- Laundered and packaged in Berkshire's ISO Class 4 cleanroom
- Gamma irradiated and validated sterile to a 10^{-6} Sterility Assurance Level per AAMI guidelines
- Pre-wetted with 70% USP Grade IPA/30% DI Water
- 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 and available on the web by lot number 24/7. Details: Date of Manufacture, Expiration Date, Radiation Dosage, Lot Information, Meets cGMP requirements for traceability
- 3-year shelf life from date of manufacture

Benefits

- Critically low particles, fibres, 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
- Lot traceability

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> <800> and Annex 1 applications
- Excellent for cleaning sterile laminar air flow units, barrier isolators and bio-containment units

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^2	**130**	TAPPI T-410
Caliper		µm	**442**	TAPPI T-411
Fibres	≥100µm	$fibres/cm^2$	**0.12**	IEST-RP-CC004.4 Sec 7.1.3/Sec 7.2.2 modified
Particles	≥0.5µm	$x10^3/cm^2$	**0.31**	IEST-RP-CC004.4 Sec 7.1.3/Sec 7.2.1 modified
Sorbency	Capacity	mL/m^2	**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/m^2	**0.0019**	IEST-RP-CC004.4 Sec 8.1.2
	IPA	g/m^2	**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**	
	Cl^-	ppm	**0.032**	

Efficacy Data

Microorganism	Log Reduction (EN16615)
Staphylococcus aureus	>6.07
Pseudomonas aeruginosa	>5.59
Enterococcus hirae	>5.72
Candida albicans	>4.32

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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 Water	Saturation	VOC % by Weight	Style
Sterile SatPax® MSVP	SSPVPR124BPR	9x9"(23x23cm)	30	24	70/30	60%	43.2	J-Fold

Other Berkshire products


Wipers


Mop Systems


Face Masks


Glove Liners


Documentation Systems


Swabs

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