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® MSVP WFI Low Endotoxin

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

BPR • AUTHORISED • BIOCIDAL PRODUCTS REGULATION

Sterile SatPax® MSVP LE is an ultrasonically sealed edge cleanroom laundered wiper recommended for ISO Class 3 and above environments. It is composed of 100% continuous filament polyester knit fabric pre-wetted with 70% USP Grade IPA and 30% WFI. This unique pre-wetted format not only provides Sterile SatPax® MSVP LE with the highest cleanliness, abrasion resistance, and chemical compatibility required for cleaning critical sterile processing environments, but also offers a cost-effective and easy-to-use solution versus traditional bulk handling of solvents and maintenance of 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.



Other Sterile, Low Endotoxin Wipers in the BPR range

- Sterile SatPax® 550 Low Endotoxin

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 sterile validated to a 10^{-6} Sterility Assurance Level per AAMI guidelines
- Pre-wetted with 70% USP Grade IPA/30% WFI
- Re-sealable solvent resistant pouches allow for single wiper use and prevent evaporation
- Each pouch has two layers of wrapping 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
- Endotoxin limit < 20 EU/device, < 0.5 EU/mL
- Each lot tested for endotoxins - Certificate of Conformity available on website
- 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 material design reduces actual cost in use compared to heavier weight products
- WFI (Water for Injection) solution for critical applications
- 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> applications and Annex 1
- 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 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	WFI 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 utilised 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/WFI	Saturation	VOC % by	Style
Sterile SatPax ® MSVP LE	SSPVP112LEBPR	9x9"(23x23cm)	30	12	70/30	60%	43.0	J-Fold

For more information on our other contamination control products or technical consultation, please contact your Berkshire Sales Representative or e-mail: **info@berkshire.com**

Other Berkshire products

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


Wipers


Mop Systems


Face Masks


Glove Liners


Documentation Systems


Swabs