

## Sterile SatPax® 550 WFI Low Endotoxin

Sterile Pre-wetted 100% Meltblown Polypropylene Low Endotoxin Cleanroom Wiper



Sterile SatPax® 550 LE wipers are composed of exceptionally clean 100% meltblown polypropylene pre-wetted with 70% USP Grade IPA and 30% WFI. This pre-wetted format provides a cost-effective and easy-to-use solution versus traditional bulk handling of solvents, maintenance of squirt bottles, and inconsistent wetting and cleaning associated with wetting a dry wiper. Each package is gamma-irradiated sterile to a 10<sup>-6</sup> Sterility Assurance Level, ensuring the highest level of sterility and making the product ideal for cleaning critical sterile processing environments.

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% meltblown polypropylene
- No chemical binders in base material
- Pre-wetted with 70% USP Grade IPA/30% WFI
- Re-sealable solvent resistant packaging
- Wipers in c-folded configuration for single withdrawal
- Gamma irradiated and sterile validated to a 10<sup>-6</sup> Sterility Assurance Level per AAMI guidelines
- Certificate of Sterility with each case and available on the web by lot number 24/7. Details: Expiration Date, Date of Manufacture, Radiation Dosage, Lot Information, Meets cGMP requirements for traceability
- Endotoxin limit < 20 EU/device, < 0.5 EU/mL
- Each lot tested for endotoxins - certificate available on website

### Benefits

- Very low extractables and ions
- Very low particle and fibre counts
- Reduces alcohol usage and preparation / handling costs
- Increases cleaning efficiency
- Increases cleaning protocol consistency
- WFI (Water for Injection) solution for critical application requiring WFI
- Lot traceability

### Environmental

- Reduces VOC (Volatile Organic Compound) emissions

### Applications

- Designed for use in ISO Class 5 and higher sterile cleanroom environments USP <797> <800>, and Annex 1 applications
- Designed for use in wet cleaning of critical surfaces where control of flammable solvents and flammable solvent concentrations is required
- Final cleaning of surfaces or products prior to manufacturing or packaging

### Other Sterile, Low Endotoxin Wipers in the BPR range

- Sterile SatPax® MicroSeal® VP Low Endotoxin

### 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<sup>-6</sup> (which is the chance of 1 non-sterile unit in 1,000,000).

[www.berkshire.uk.com](http://www.berkshire.uk.com)

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## Technical Data (In Dry State)

Attribute		Units	Value	Test Method
Basis Weight		g/m <sup>2</sup>	35.4	TAPPI T-410
Caliper		µm	204	TAPPI T-411
Fibres	≥100µm	fibres/cm <sup>2</sup>	0.48	TEST-RP-CC004.4 Sec 7.1.3/Sec 7.2.2 modified
Particles	≥0.5µm	x10 <sup>3</sup> /cm <sup>2</sup>	4.8	TEST-RP-CC004.4 Sec 7.1.3/Sec 7.2.1 modified
Sorbency	Capacity	mL/m <sup>2</sup>	196*	TEST-RP-CC004.4 Sec 9.1 / Sec 9.2 modified Sorbency Capacity, Efficiency, and Rate are performed with 70% IPA
	Efficiency	mL/g	5.5*	
	Rate	seconds	10*	
Non-Volatile Residue	DI Water	g/m <sup>2</sup>	0.0032	EST-RP-CC004.4 Sec 8.1.2
	IPA	g/m <sup>2</sup>	0.015	
Ions	Na <sup>+</sup>	ppm	0.42	TEST-RP-CC004.4 Sec 8.2.2
	K <sup>+</sup>	ppm	0.20	
	Ca <sup>++</sup>	ppm	0.47	
	Mg <sup>++</sup>	ppm	0.038	
	Cl <sup>-</sup>	ppm	0.80	

## Efficacy Data

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

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### Notes:

- Technical data represented in this table are typical values 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® 550 LE	SSP550524LEBPR	9x11" (23x28cm)	50	24	70/30	60%	48	C-fold

## Other Berkshire Products



Wipers



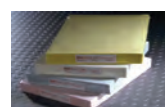
Mop Systems



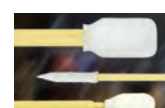
Face Masks



Glove Liners



Documentation Systems



Swabs