Berkshire
ENGINEERED CLEAN

Product Information
ISO Class 5 – 8
Cleanroom Class 100 – 100,000
EU Grade A/B/C/D
USP <797> <800>, Annex 1

Sterile SatPax® 550 WFI Low Endotoxin

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

BPR • AUTHORISED • BIOCIDAL PRODUCTS REGULATION

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^{-6} 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.



Other Sterile, Low Endotoxin Wipers in the BPR range

- Sterile SatPax®MicroSeal®VP Low Endotoxin

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^{-6} 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 of Conformity available on website
- 3-year shelf life from date of manufacture

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

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	**35.4**	TAPPI T-410
Caliper		µm	**204**	TAPPI T-411
Fibres	≥100µm	$fibres/cm^2$	**0.48**	IEST-RP-CC004.4 Sec 7.1.3/Sec 7.2.2 modified
Particles	≥0.5µm	$x10^3/cm^2$	**4.8**	IEST-RP-CC004.4 Sec 7.1.3/Sec 7.2.1 modified
Sorbency	Capacity	mL/m^2	**196***	IEST-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^2	**0.0032**	EST-RP-CC004.4 Sec 8.1.2
	IPA	g/m^2	**0.015**	
Ions	Na^+	ppm	**0.42**	IEST-RP-CC004.4 Sec 8.2.2
	K^+	ppm	**0.20**	
	Ca^{++}	ppm	**0.47**	
	Mg^{++}	ppm	**0.038**	
	Cl^-	ppm	**0.80**	

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 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


Glove Liners


Mop Systems


Documentation Systems


Face Masks


Swabs