

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% IPA and 30% DI water. 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 making the product ideal for cleaning critical sterile processing environments.



Key Attributes

- 100% meltblown polypropylene
- No chemical binders in base material
- Pre-wetted with 70% USP Grade IPA
- 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, 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 fiber 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

Environmental

- Reduces VOC (Volatile Organic Compound) emissions
- Complies with RoHS
- Registered under REACH

Applications

- Designed for use in ISO Class 5 and higher sterile cleanroom environments
- 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

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 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).

Other Sterile, Low Endotoxin Wipers

- Gamma Wipe® Microfirst® LP LE
- MicroSeal® VP LE
- MicroSeal® SuperSorb® LE

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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
Fibers	≥100μm	fibers/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
	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	

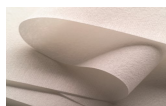
Notes:

- 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
- *Sorbency Capacity, Efficiency, and Rate are performed with 70% IPA

Order Information:

Product	Number	Size	Shts/pk	Pks/cs	IPA/DI	VOC % by Weight	Style
Sterile SatPax® 550 LE	SSP55000524LE	9x11" (23x28cm)	50	24	70/30	48%	C-fold

Other Berkshire Products



Wipers



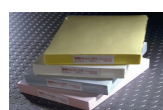
Mop Systems



Face Masks



Glove Liners



Documentation Systems



Swabs