

USP 797 & 800 Compliance Specialists

Everything you need to achieve and maintain a compliant cleanroom environment

Sterile SatPax® 550

Sterile Pre-wetted 100% Meltblown Polypropylene Cleanroom Wiper

Product Information

ISO Class 5 - 8

Cleanroom Class 100 – 100,000@ EU Grade A/B/C/D

Sterile SatPax® 550 wipers are composed of exceptionally clean100% 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 polyropylene
- · No chemical binders in base material
- Pre-wetted with consistent 70% IPA/ 30% DI Water
- · 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

Benefits

- Very low extractables and ions
- · Very low particle and fiber counts
- Reduces alcohol usage and preparation / handling costs
- · Reduces VOC emissions
- · Increases cleaning efficiency
- Increases cleaning protocol consistency

Environmenta

- Reduces VOC (Volatile Organic Compound) emissions
- Complies with RoHS and pre-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).









Carter-Health Disposables, LLC

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Technical Data (In Dry State)

Attribute		Units	Value	Test Method		
Basis Weight		g/m²	37.3	TAPPI T-410		
Caliper		μm	199	TAPPI T-411		
Fibers	≥100µm	fibers/cm ²	0.36	IEST-RP.CC004.3, Sec 6.1.3 / Sec 6.2.2		
Particles	<u>></u> 0.5µm	x10 ³ /cm ²	1.5	IEST-RP.CC004.3, Sec 6.1.3 / Sec 6.2.1		
Sorbency	Capacity	mL/m²	213*	IEST-RP.CC004.3, Sec 8.1 modified / Sec 8.2 modified		
	Efficiency	mL/g	5.7*			
	Rate	seconds	10*			
Non-Volatile Residue	DI Water	g/m²	0.0012	IEST-RP.CC004.3, Sec 7.1.2		
	IPA	g/m²	0.00050			
Ions	Na ⁺	ppm	5.3	IEST-RP.CC004.3, Sec 7.2.2		
	K ⁺	ppm	0.19			
	Ca ⁺⁺	ppm	0.33			
	Mg ⁺⁺	ppm	0.14			
	CI-	ppm	2.7			

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	Style
Sterile SatPax® 550	SSP55000424	9x11" (23x28cm)	50	24	70/30	48%	C-fold
Sterile SatPax® 550	SSP55000524	7x11" (18x28cm)	50	24	70/30	48%	C-fold



