

Product Information

ISO Class 3 - 5

Cleanroom Class 1 – 100 EU Grade A/B/C/D

# Sterile SatPax® MicroSeal® WFI

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

Sterile SatPax® MicroSeal® WFl combines MicroSeal® 1200 This pre-wetted format provides a cost effective and ultrasonically sealed edge cleanroom laundered wipers composed of 100% continuous filament polyester knit fabric with a high saturation level of 70% IPA and 30% WFI water.

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 then gamma irradiated sterile to a 10<sup>-6</sup> Sterility Assurance Level making the product ideal for cleaning critical sterile processing environments.



#### Other Sterile Pre-wetted wipers

- Sterile SatPax® 670
- Sterile SatPax® 1000
- Sterile SatPax® 1200

# **Key Attributes**

- 100% continuous filament polyester knit
- Ultrasonically sealed edge for reduced fiber contamination
- Laundered and packaged in Berkshire's ISO Class 4 cleanroom
- Pre-wetted with consistent 70% IPA/ 30% WFI (Water for Injection) to a high saturation level
- Re-sealable solvent resistant packaging
- Triple packaged for easy entry into sterile environments
- 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, Radiation Dosage, Lot Information, Meets cGMP requirements for traceability

- Critically low fibers, particles, ions and extractables combined with high abrasion resistance
- WFI (Water for Injection) solution for critical applications requiring WFI
- Reduces alcohol usage and preparation / handling costs
- Reduces VOC emissions
- Increases cleaning efficiency
- Increases cleaning protocol consistency

### **Environmental**

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

# **Applications**

- Designed for use in ISO Class 3 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
- High saturation level is ideal for removing cleaning and disinfecting residues in sterile environments

#### **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).

# www.berkshire.com

Contact: Tel 1 800 242 7000 / 1 413 528 2602 info@berkshire.com

Americas	Tel 1 413 528 2602	Fax 1 413 528 2614	info@berkshire.com
Europe	Tel 44 (0) 870 757 2877	Fax 44 (0) 870 757 2878	enquiries@berkshire.uk.com
SE Asia	Tel 65 6252 4313	Fax 65 6252 4312	enquiries@berkshire.com.sg
Japan	Tel 81 3 5827 2380	Fax 81 3 5827 2382	master@berkshire.co.jp



# **Technical Data (In Dry State)**

Attribute		Units	Value	Test Method
Basis Weight		g/m²	154	TAPPI T-410
Caliper		μm	507	TAPPI T-411
Fibers	<u>≥</u> 100μm	fibers/cm <sup>2</sup>	0.036	IEST-RP-CC004.3, Sec 6.1.3 / Sec 6.2.2
Particles	<u>≥</u> 0.5µm	x10³/cm²	0.40	_IEST-RP-CC004.3, Sec 6.1.3 / Sec 6.2.1
Sorbency	Capacity	mL/m²	512	IEST-RP-CC004.3, Sec 8.1 modified / Sec 8.2 modified
	Efficiency	mL/g	3.3	
	Rate	seconds	1	
Non-Volatile Residue	DI Water	g/m²	0.045	IEST-RP-CC004.3, Sec 7.1.2
	IPA	g/m²	0.0082	
Ions	Na <sup>+</sup>	ppm	0.17	IEST-RP-CC004.3, Sec 7.2.2
	K <sup>+</sup>	ppm	0.010	
	Ca <sup>++</sup>	ppm	0.046	
	Mg <sup>++</sup>	ppm	0.011	
	CI-	ppm	0.30	

#### 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/WFI	Saturation	VOC % by Weight	Style
Sterile SatPax® MS-WFI	SSPMS.01.5WFI	12x12" (30x30cm)	50	5	70/30	60%	42%	Flat Pack

# Other Berkshire Products



Wipers



**Glove Liners** 



**Mop Systems** 



**Documentation Systems** 



**Face Masks** 



Swabs