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® 1000

Sterile Pre-wetted 55% Cellulose / 45% Polyester Nonwoven Cleanroom

BPR • AUTHORISED • BIOCIDAL PRODUCTS REGULATION

Sterile SatPax® 1000 combines Durx® 670 nonwoven wipers composed of a hydroentangled nonwoven blend of 55% cellulose and 45% polyester with a high saturation level of 70% USP Grade 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 then gamma irradiated sterile to a 10^{-6} Sterility Assurance Level 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 Pre-wetted wipers in the BPR range

- Sterile SatPax® 670

Key Attributes

- 55% cellulose / 45% polyester hydroentangled nonwoven blend
- No chemical binders in base material
- Pre-wetted with consistent 70% USP Grade 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: Date of Manufacture, Expiration Date, Radiation Dosage, Lot Information, Meets cGMP requirements for traceability
- 3-year shelf life from date of manufacture

Benefits

- Low extractables and fibre and particle counts
- Smooth and durable with good wet strength
- Reduces alcohol usage and preparation / handling costs
- Reduces VOC emissions
- Increases cleaning efficiency
- Increases cleaning protocol consistency

Applications

- Designed for use in ISO Class 5 and higher sterile cleanroom environments and in 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
- High saturation level is ideal for removing cleaning and disinfecting residues in sterile environments

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	**68.0**	TAPPI T -410
Caliper		µm	**264**	TAPPI T -411
Fibers	≥100µm	$fibers/cm^2$	**160**	IEST -RP -CC004.4 Sec 7.1.3 /Sec 7.2.2 modified
Particles	≥0.5µm	$x10^3/cm^2$	**10**	IEST -RP -CC004.4 Sec 7.1.3 /Sec 7.2.1 modified
Sorbency	Capacity	mL/m^2	**320**	IEST -RP -CC004.4 Sec 9.1 /Sec 9.2 modified
	Efficiency	mL/g	**4.7**	
	Rate	seconds	**2**	
Non-Volatile Residue	DI Water	g/m^2	**0.028**	IEST -RP -CC004.4 Sec 8.1.2
	IPA	g/m^2	**0.0038**	
Ions	Na^+	ppm	**62**	IEST -RP -CC004.4 Sec 8.2.2
	K^+	ppm	**5.9**	
	Ca^{++}	ppm	**22**	
	Mg^{++}	ppm	**5.0**	
	Cl^-	ppm	**31**	

Efficacy Data

Microorganism	Log Reduction (EN16615)
Staphylococcus aureus	>6.07
Pseudomonas aeruginosa	>5.30
Enterococcus hirae	5.56
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 utilised 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®	SSP1000124BPR	9x9" (23x23cm)	30	24	70/30	60%	44	C-fold

Other Berkshire products



Wipers



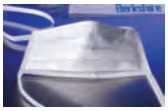
Glove Liners



Mop Systems



Documentation Systems



Face Masks



Swabs

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