

Sterile SatPax[®] 1000

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



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.



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 available to download on the web by lot number 24/7. Details: Date of Manufacture, Expiration Date, Radiation Dosage, Lot Information, Meets cGMP requirements for traceability

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

Other Sterile Pre-wetted wipers in the BPR range

- Sterile SatPax[®] 670

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) |
|-------------------------------|-------------------------|
| <i>Staphylococcus aureus</i> | >6.07 |
| <i>Pseudomonas aeruginosa</i> | >5.30 |
| <i>Enterococcus hirae</i> | 5.56 |
| <i>Candida albicans</i> | >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