

Sterile SatPax[®] MicroSeal[®]-VP

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



Sterile SatPax[®] MicroSeal[®]-VP is an ultrasonically sealed edge cleanroom-laundered wiper recommended for ISO Class 3 and above environments, made of 100% continuous filament polyester knit fabric. The wiper is pre-wetted with 70% USP Grade IPA and 30% DI Water. Each package is gamma-irradiated sterile to a 10⁶ Sterility Assurance Level. This combination of properties provides Sterile SatPax[®] MicroSeal[®]-VP with the highest level of cleanliness, abrasion resistance, and chemical compatibility required for cleaning critical sterile processing environments. The pre-wetted format offers a cost-effective and easy-to-use solution compared to the bulk handling of solvents and the maintenance of traditional squirt bottles.

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

- 100% continuous filament polyester knit
- Ultrasonically sealed edge for reduced fibre contamination
- Laundered and packaged in Berkshire's ISO Class 4 cleanroom
- Gamma irradiated and validated sterile to a 10⁶ Sterility Assurance Level per AAMI guidelines
- Pre-wetted with 70% USP Grade IPA/30% DI Water
- Peel and reseal pouches allow for single wiper use and prevent evaporation
- Double wrapped for easy entry into sterile environments
- Certificate of Sterility with each case. Details: Date of Manufacture, Expiration Date, Radiation Dosage, Lot Information, Meets cGMP requirements for traceability

Benefits

- Critically low particles, fibres, ions and extractables
- High abrasion resistance
- High Absorbency
- Increases cleaning protocol consistency
- Light weight, high absorbency material design reduces actual cost in use compared to heavier weight products
- Lot traceability

Applications

- Designed for use in ISO Class 3 and higher sterile environments where microbial exclusion is demanded
- Designed for cleaning sterile surfaces and equipment during aseptic processing and USP <797> <800> and Annex 1 applications
- Excellent for cleaning sterile laminar air flow units, barrier isolators and bio-containment units

Validated Sterile

ANSI/AAMI/ISO procedures have been followed for verification of irradiation dose with quarterly 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).

Technical Data (In Dry State)

| Attribute | | Units | Value | Test Method |
|----------------------|------------------|-----------------------------------|--------|--|
| Basis Weight | | g/m ² | 130 | TAPPI T-410 |
| Caliper | | µm | 442 | TAPPI T-411 |
| Fibres | ≥100µm | fibres/cm ² | 0.12 | IEST-RP-CC004.4 Sec 7.1.3/Sec 7.2.2 modified |
| Particles | ≥0.5µm | x10 ³ /cm ² | 0.31 | IEST-RP-CC004.4 Sec 7.1.3/Sec 7.2.1 modified |
| Sorbency | Capacity | mL/m ² | 448 | IEST-RP-CC004.4 Sec 9.1 / Sec 9.2 modified |
| | Efficiency | mL/g | 3.4 | |
| | Rate | seconds | 1 | |
| Non-Volatile Residue | DI Water | g/m ² | 0.0019 | IEST-RP-CC004.4 Sec 8.1.2 |
| | IPA | g/m ² | 0.0054 | |
| Ions | Na ⁺ | ppm | 0.17 | IEST-RP-CC004.4 Sec 8.2.2 |
| | K ⁺ | ppm | 0.024 | |
| | Ca ⁺⁺ | ppm | 0.053 | |
| | Mg ⁺⁺ | ppm | 0.011 | |
| | Cl ⁻ | ppm | 0.032 | |

Efficacy Data

| Microorganism | Log Reduction (EN16615) |
|-------------------------------|-------------------------|
| <i>Staphylococcus aureus</i> | >6.07 |
| <i>Pseudomonas aeruginosa</i> | >5.59 |
| <i>Enterococcus hirae</i> | >5.72 |
| <i>Candida albicans</i> | >4.32 |

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Notes:

- Technical data represented in this table are typical value 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/DI Water | Saturation | VOC % by Weight | Style |
|----------------------|--------------|---------------|---------|--------|--------------|------------|-----------------|--------|
| Sterile SatPax® MSVP | SSPVPR124BPR | 9x9"(23x23cm) | 30 | 24 | 70/30 | 60% | 43.2 | J-Fold |

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