

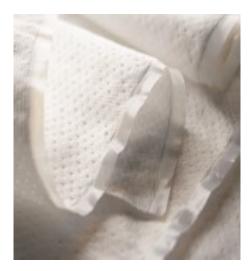
Product Information ISO Class 3 – 5 Cleanroom Class 1 – 1000 EU Grade A/B/C/D

Gamma Wipe[®] 300

Sterile Sealed Edge Cleanroom Laundered 100% Polyester

Gamma Wipe® 300 is a high sorbency, tubular, sealed edge Each package is gamma irradiated sterile to a 10-6 cleanroom laundered two-ply wiper recommended for ISO Class 3 and above environments composed of 100% continuous filament polyester knit fabric.

Sterility Assurance Level. This combination of properties provides Gamma Wipe® 300 with the highest level of cleanliness, abrasion resistance and chemical compatibility required for cleaning critical sterile processing environments.



Other Sterile wipers

- Gamma Wipe SuperSorb®
- Gamma Wipe® 120
- Gamma Wipe[®] 67

Key Attributes

- 100% continuous filament polyester knit
- Two-ply pinsonic tubular construction
- Patented sealed edge process for reduced fiber contamination; Patent #5,229,181
- Laundered and packaged in Berkshire's ISO Class 4 cleanroom with Lot Number on each pack
- Gamma irradiated and sterile validated to a 10⁻⁶ Sterility Assurance Level per AAMI guidelines •
- Header style packaging with Package Integrity testing
- Certificate of Sterility available to be down loaded on the web by lot number 24/7. Details: Expiration Date, Radiation Dosage, Lot Information, Meets cGMP requirements for traceability

Benefits

- Critically low particles, fibers, ions and extractables
- High absorbency
- Pinsonic design adds surface texture that aids in stubborn residue removal •
- Patented sealed edge process combined with tubular design offers excellent abrasion resistance for the toughest cleaning applications
- Chemically compatible with common cleaning and disinfecting solutions including isopropyl alcohol, phenols, bleaches and quarternary ammonium compounds

Environmental

Complies with RoHS

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

Pre-Wetted Option

The same wiper material can be provided in pre-wetted formats for reduced VOC emissions, increased convenience, increased productivity, improved solvent control and cleaning protocol repeatability and reduced costs. Pre-wetted options include WFI.

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).

Fax 81 3 5827 2382

master@berkshire.co.jp

www.berkshire.eu.com	America	Tel 1 413 528 2602	Fax 1 413 528 2614	info@berkshire.com
Contact: Tel 44 (0) 870 757 2877	Europe	Tel 44 (0) 870 757 2877	Fax 44 (0) 870 757 2878	enquiries@berkshire.uk.com
enquiries@berkshire.uk.com	SE Asia	Tel 65 6252 4313	Fax 65 6252 4312	enquiries@berkshire.com.sg

Japan

Tel 81 3 5827 2380



Technical Data:

Attribute		Units	Value	Test Method
Basis Weight		g/m ²	189	TAPPI T-410
Caliper		μm	552	TAPPI T-411
Fibers	≥100µm	fibers/cm ²	0.0075	IEST-RP-CC004.3, Sec 6.1.3 / Sec 6.2.2
Particles	≥ 0. 5µm	x10 ³ /cm ²	0.55	IEST-RP-CC004.3, Sec 6.1.3 / Sec 6.2.1
Sorbency	Capacity	mL/m	522	IEST-RP-CC004.3, Sec 8.1 modified / Sec 8.2 modified
	Efficiency	mL/g	2.8	
	Rate	seconds	1	
Non-Volatile Residue	DI Water	g/m²	0.0047	IEST-RP-CC004.3, Sec 7.1.2
	IPA	g/m ²	0.025	
Ions	Na ⁺	ppm	0.0049	IEST-RP-CC004.3, Sec 7.2.2
	K+	ppm	0.041	
	Ca++	ppm	0.0086	
	Mg ⁺⁺	ppm	0.0025	
	CI-	ppm	0.023	

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 part testing are be applied and equipment.
- Third party testing can be performed upon request

Order Information:

Product	Number	Size	Shts/pk	Pks/Inner bag	Inner bags/cs	Pks/cs	Style
Gamma Wipe [®] 300	GW300.ST.25	12x12"(30x30cm)	10	5	5	25	Header Bag

 Other Berkshire Products
 Wipers
 Image: Construction of the second s

www.berkshire.eu.com Contact: Tel 44 (0) 870 757 2877 / enquiries@berkshire.uk.com BIL_3020_08-2019