

Product Information ISO Class 5 — 8 Cleanroom Class 100 – 100,000 EU Grade A-D USP <797>

Gamma Wipe[®] 67 Sterile Polyester / Cellulose Nonwoven Wiper

Gamma Wipe®67 is a polyester / cellulose blend wiper recommended for ISO Class 5 and above environments composed of 45% polyester and 55% cellulose. Each package is gamma irradiated to a 10⁻⁶ Sterility Assurance.

This combination of properties provides Gamma Wipe® 67 cleanliness are required. with the level of cleanliness, abrasion resistance and chemical compatibility required for cleaning general sterile processing areas where both economy and



Other Sterile wipers

- Gamma Wipe SuperSorb®
- Gamma Wipe® 300
- Gamma Wipe® 120

Key Attributes

- 55% cellulose / 45% polyester hydroentangled nonwoven
- No secondary binders
- Gamma irradiated and sterile validated to a 10⁻⁶ Sterility Assurance Level per AAMI guidelines
- Header style packaging with Package Integrity testing
- Lot number on each pack
- 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

Benefits

- Excellent combination of the synthetic polyester strength and cleanliness with the absorbent characteristics of cellulose.
- Smooth, highly absorbent and durable with low extractable levels
- Economical
- Chemically compatible with common cleaning and disinfecting solutions including isopropyl alcohol, phenols, bleaches and quarternary ammonium compounds

Environmental

- Complies with RoHS 2002/05 and REACH requirements
- 55% cellulose fiber content is biodegradable

Applications

- Designed for use in ISO Class 5 and higher sterile environments and USP <797> applications
- Designed for cleaning sterile surfaces and equipment during aseptic processing
- · General wiping in component prep, compounding and wash areas
- General wipedowns in sterile gowning rooms
- Applying and removing cleaning and disinfecting solutions

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 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).

La la la la comunicación de la comu				
www.berkshire.com Contact: Tel 1 800 242 7000 / 1 413 528 2602 info@berkshire.com	America	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:

Attribute		Units	Value	Test Method	
Basis Weight		g/m ²	67.6	TAPPI T-410	
Caliper		μm	243	TAPPI T-411	
Fibers	≥100µm	fibers/cm ²	200	IEST-RP.CC004.3, Sec 6.1.3 / Sec 6.2.2	
Particles	≥0.5µm	x10 ³ /cm ²	16	IEST-RP.CC004.3, Sec 6.1.3 / Sec 6.2.1	
Sorbency	Capacity	mL/m ²	291	IEST-RP.CC004.3, Sec 8.1 modified / Sec 8.2 modified	
	Efficiency	mL/g	4.3		
	Rate	seconds	2		
Non-Volatile Residue	DI Water	g/m ²	0.030	IEST-RP.CC004.3, Sec 7.1.2	
	IPA	g/m ²	0.0034		
lons	Na ⁺	ppm	49	IEST-RP.CC004.3, Sec 7.2.2	
	K ⁺	ppm	4.1		
	Ca++	ppm	12		
	Mg ⁺⁺	ppm	4.7		
	Cl	ppm	39		

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	Style
Gamma Wipe [®] 67	GW67.ST.25	12x12"(30x30cm)	20	25	Header Bag

For more information on our other contamination control products or technical consultation, please contact your Berkshire Sales Representative or e-mail: <u>info@berkshire.com</u>

