# LOW ENDOTOXIN WIPES

Berkshire's new line of low endotoxin cleanroom wipes have been engineered to meet the specific requirements of the pharmaceutical, healthcare and medical device industries.

#### What is a pyrogen (endotoxin)?

IEST-RP-CC023.2 defines a pyrogen as "A substance capable of producing fevers. The most common pyrogens are endotoxins, a class of lipopolysaccharides that comprise the outer wall of Gram-negative bacteria and are themselves byproducts of cell metabolism."

Endo - Internal Toxin - Poison

Lipid A is the most toxic component of a gram-negative bacteria. It is embedded internally in the living bacteria.

When bacteria is killed through cleaning, the outer cell wall detritus is released and the dead cell becomes toxic. It needs to be removed from the surface.

#### What are common sources of endotoxins?

Common sources of endotoxins are water, soil, vegetation, raw materials, poor equipment sanitization and maintenance practices.

#### What are examples of gram-negative endotoxins?

Burkholderia, Pseudomonas, Ralstonia, Escherichia, Serratia, Stenotrophomonas

#### How do you test wipers for bacterial endotoxins?

Berkshire uses the LAL - Limulus Amebocyte Lysate test.

FDA Guidance for Industry: Pyrogen and Endotoxins Testing

"For more than 30 years, FDA has accepted the use of Limulus Amoebocyte Lysate LAL test for endotoxins in lieu of the rabbit pyrogens test."

#### What is the frequency of endotoxin testing?

Berkshire tests each lot for endotoxins.

#### What are your guaranteed endotoxin limits?

<20 EU/device - <0.5 EU/mL

FDA Guidance for Industry: Pyrogen and Endotoxins Testing

"For medical devices...the limit is 0.5 EU/mL or 20 EU/ device for products that directly or indirectly contact the cardiovascular system and lymphatic system'

#### How is the Water For Injection (WFI) prepared?

The WFI is prepared by a validated aseptic sterile filtration process. This complies with the industry's Sterility Assurance Level (SAL) of 10-3. The specification for Endotoxin USP is ≤0.025 EU/mL.

#### **PRICING & AVAILABILITY**

To learn more about Berkshire's low endotoxin wipes, contact your Technical Sales Representative, call 800-242-7000 or visit www.berkshire.com for a guick online chat.



### **BERKSHIRE CORPORATION**

IIEM NUMBER	PRODUCT/ PACKAGING
Sealed edge, clea dry wiper	nroom laundered, polyester knitted,
MSVP09098LE	<b>MicroSeal® VP – 9x9"</b> (22x22cm) 150 SHTS /PK, 8 PKS/CS
MSSS09098LE	MicroSeal SuperSorb® – 9x9" (22x22cm) 100 SHTS /PK, 8 PKS/CS
Sterile, sealed ed knitted, dry wiper	ge, cleanroom laundered, polyester
GWSSST16LE	<b>Gamma® Wipe SuperSorb® – 12x12"</b> (30x30cm), 10 SHTS /PK, 16 PKS/CS
GWVPST25LE	<b>Gamma Wipe® VP – 12x12"</b> (30x30cm) 20 SHTS /PK, 25 PKS/CS
Sealed edge, clea presaturated WFI	nroom laundered, polyester knitted, wiper
SPXVP00112LE	<b>SatPax® MSVP – 9x9″</b> (22x22cm) 30 SHTS /PK, 12 PKS/CS
Sterile, sealed ed ted, presaturated	ge, cleanroom laundered, polyester knit- WFI wiper
SSPVP00112LE	Sterile SatPax® MSVP – 9x9" (22x22cm) 30 SHTS /PK, 12 PKS/CS
Nonwoven, dry w	iper
MFLP090912LE	<b>MicroFirst® LP – 9x9"</b> (22x22cm) 150 SHTS /PK, 12 PKS/CS
Sterile, Nonwove	n, dry wiper
GWMFLPST25LE	<b>Gamma Wipe® MFLP – 12x12"</b> (30x30cm) 20 SHTS /PK, 25 PKS/CS
GWMPNW5ST25LE	<b>Gamma Wipe® MPNW – 12x12"</b> (30x30cm) 20 SHTS /PK, 25 PKS/CS
Nonwoven, presa	turated WFI wiper
SPXMFLP00112LE	<b>SatPax® MFLP – 9x9″</b> (22x22cm) 75 SHTS /PK, 12 PKS/CS
SPX55000624LE	<b>SatPax® 550 – 9x11″</b> (22x28cm) 50 SHTS /PK, 24 PKS/CS
Sterile, nonwover	n, presaturated WFI wiper
	Sterile SatPax® MFLP – 9x9" (22x22cm)

	30 SHTS /PK, 24 PKS/CS
SSP55000524LE	Sterile SatPax® 550 –9x11" (22x28cm) 50 SHTS /PK, 24 PKS/CS

## LOW ENDOTOXIN VITAL STATISTICS BY SUBSTRATE

## **100% POLYESTER KNITTED 2-PLY WIPER**

	BASIS WEIGHT	CALIPER	FIBERS	PARTICLES ≥ 0.5µm	SORBENCY			NON-VOLATI	LE RESIDUE	IONS					
ITEM NUMBER	g/m <sub>2</sub>	μm	≥100µm/cm <sup>2</sup>	x10 <sup>3</sup> /cm <sup>2</sup>	<b>CAPACITY</b> mL/m <sup>2</sup>	EFFICIENCY mL/g	RATE SECONDS	H <sub>2</sub> O (g/m <sup>2</sup> )	<b>IPA (g/m²)</b>	Na⁺	K⁺	Ca <sup>++</sup>	Mg <sup>++</sup>	CI	
GWSSST16LE	265	777	0.14	0.51	1010	3.8	1	0.010	0.014	0.30	0.028	0.023	0.051	0.13	
MSSS09098LE	265	777	0.14	0.51	1010	3.8	1	0.010	0.014	0.30	0.028	0.023	0.051	0.13	

## **100% POLYESTER KNITTED WIPER**

	BASIS WEIGHT	CALIPER	FIBERS	PARTICLES ≥ 0.5µm	SORBENCY			NON-VOLATI	LE RESIDUE	IONS					
ITEM NUMBER	g/m <sub>2</sub>	μm	≥100µm/cm <sub>2</sub>	x10 <sup>3</sup> /cm <sup>2</sup>	<b>CAPACITY</b> mL/m <sup>2</sup>	EFFICIENCY mL/g	RATE SECONDS	H <sub>2</sub> O (g/m²)	IPA (g/m²)	Na <sup>+</sup>	K⁺	Ca++	Mg <sup>++</sup>	CI	
GWVPST25LE	130	442	0.12	0.31	448	3.8	1	0.0019	0.0054	0.17	0.024	0.053	0.011	0.032	
MSVP09098LE	130	442	0.12	0.31	448	3.8	1	0.0019	0.0054	0.17	0.024	0.053	0.011	0.032	
SPXVP00112LE	130	442	0.12	0.31	448	3.8	1	0.0019	0.0054	0.17	0.024	0.053	0.011	0.032	
SSPVP00112LE	130	442	0.12	0.31	448	3.8	1	0.0019	0.0054	0.17	0.024	0.053	0.011	0.032	

## **100% POLYESTER MICROFIBER NONWOVEN WIPER**

	BASIS WEIGHT	CALIPER	FIBERS	PARTICLES ≥ 0.5µm	SORBENCY			NON-VOLATI	LE RESIDUE	IONS					
ITEM NUMBER	g/m <sub>2</sub>	μm	≥100µm/cm <sup>2</sup>	<b>x10<sup>3</sup>/cm<sup>2</sup></b>	<b>CAPACITY</b> mL/m <sup>2</sup>	<b>EFFICIENCY</b> mL/g	RATE SECONDS	H <sub>2</sub> O (g/m²)	<b>IPA (g/m²)</b>	Na <sup>+</sup>	K+	Ca <sup>++</sup>	Mg⁺⁺	CI	
GWMPNW5ST25LE	52.2	198	18.8	1.6	234	4.5	6.0	0.0044	0.0040	37	5.3	48	9.3	48	

## 58% POLYESTER / 42% LYOCELL NONWOVEN WIPER

	BASIS WEIGHT	Caliper	FIBERS	PARTICLES ≥ 0.5µm	SORBENCY			NON-VOLATI	LE RESIDUE	IONS					
ITEM NUMBER	g/m <sub>2</sub>	μm	≥100µm/cm <sup>2</sup>	<b>x10<sup>3</sup>/cm<sup>2</sup></b>	<b>CAPACITY</b> mL/m <sup>2</sup>	EFFICIENCY mL/g	RATE SECONDS	H <sub>2</sub> O (g/m²)	IPA (g/m²)	Na <sup>+</sup>	K⁺	Ca <sup>++</sup>	Mg⁺⁺	CI	
GWMFLPST25LE	70.2	299	20	4.1	377	5.4	3	0.021	0.0092	13	1.2	20	5.8	11	
MFLP090912LE	70.2	299	20	4.1	377	5.4	3	0.021	0.0092	13	1.2	20	5.8	11	
SPXIMFLP00112LE	70.2	299	20	4.1	377	5.4	3	0.021	0.0092	13	1.2	20	5.8	11	
SSPMFLP00124LE	70.2	299	20	4.1	377	5.4	3	0.021	0.0092	13	1.2	20	5.8	11	

## **100% POLYPROPYLENE NONWOVEN WIPER**

	BASIS WEIGHT	CALIPER	FIBERS	PARTICLES ≥ 0.5µm	SORBENCY			NON-VOLATI	LE RESIDUE	IONS					
ITEM NUMBER	g/m²	μm	≥100µm/cm <sup>2</sup>	<b>x10<sup>3</sup>/cm<sup>2</sup></b>	<b>CAPACITY</b> mL/m <sup>2</sup>	EFFICIENCY mL/g	RATE SECONDS	H <sub>2</sub> O (g/m²)	<b>IPA (g/m²)</b>	Na <sup>+</sup>	K⁺	Ca++	Mg <sup>++</sup>	CI	
SSP55000524LE	35.4	204	0.48	4.8	196*	5.5*	10*	0.0032	0.015	0.42	0.2	0.47	0.038	0.8	
SPX55000624LE	35.4	204	0.48	4.8	196*	5.5*	10*	0.0032	0.015	0.42	0.2	0.47	0.038	0.8	

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.

