

# Sterile Polynit Heatseal Low Endotoxin Wipes

## 100% no-run interlock knit polyester low endotoxin wipes with sealed edges

The presence of pyrogens is a critical safety concern for injectable products and medical devices as products contaminated with pyrogens can pose a life-threatening risk to patients. Unlike viable microbial contaminants which can be destroyed by various sterilization techniques, pyrogens are difficult to remove and deactivate. Bacterial endotoxin, specifically from the outer membranes of gram negative bacteria, are the most common pharmaceutical pyrogens.

Using low endotoxin wipes during manufacturing reduces the potential for pyrogen contamination in the most critical of applications.



Sterile Polynit Heatseal Low Endotoxin wipes are manufactured from high quality 100% knitted polyester fabric with sealed edges and produce low levels of particles and fibers. The wipes have a guaranteed endotoxin level of less than 1 EU per wipe and are validated sterile to  $10^{-6}$  SAL, making them ideal for use in product contact areas.

The wipes are half folded and triple packaged in linear tear outer bags for ease of transfer into ISO Class 5 cleanrooms. This smaller packaging takes up less space making it ideal for use in isolators and RABS. The small quantity of wipes per package can be used during one cleaning session, eliminating waste.



Features	Benefits
100% laundered knitted polyester	<ul style="list-style-type: none"> <li>• Very low levels of particles and fibers</li> <li>• Good abrasion and chemical resistance</li> </ul>
Laser sealed edges	<ul style="list-style-type: none"> <li>• Reduces fiber generation from the edge of the wipe</li> </ul>
Guaranteed endotoxin levels of <1 EU per wipe	<ul style="list-style-type: none"> <li>• Suitable for use in product contact areas</li> </ul>
Validated sterile or gamma irradiated to >25kGY	<ul style="list-style-type: none"> <li>• Suitable for use in ISO Class 5 (Grades A/B) cleanrooms</li> </ul>
Small number of wipes per bag	<ul style="list-style-type: none"> <li>• Eliminates waste, all wipes will be used in one session</li> </ul>
Triple packed in linear tear bags	<ul style="list-style-type: none"> <li>• Easy to open and transfer into isolator and RABS</li> </ul>

Part No.	Description		Size	Packaging
LWLE0001	Sterile Polynit Heatseal Low Endotoxin Wipes, half folded, triple bagged		9" x 9" (230 x 230 mm)	10/bag; 50 bags/case
LWLE0002	Sterile Polynit Heatseal Low Endotoxin Wipes, half folded, triple bagged		12" x 12" (305 x 305 mm)	10/bag; 36 bags/case

Product Information	
Material	<ul style="list-style-type: none"> <li>100% polyester</li> </ul>
Construction	<ul style="list-style-type: none"> <li>Interlock knit, no-run</li> </ul>
Packaging materials	<ul style="list-style-type: none"> <li>Outer bags (OB1, OB2, OB3), low density polyethylene (LDPE) </li> <li>Case (CS), corrugated fiberboard (PAP) </li> </ul>
Environment	<ul style="list-style-type: none"> <li>ISO 3-8 Grade A/B</li> </ul>



Recycle Symbols



Technical Data		
Attribute (units)	Typical Value	Test Method
Basis weight, nominal; (g/m <sup>2</sup> )	140	Contec Method
Sorbent capacity; (mL/m <sup>2</sup> )	503	IEST-RP-CC004.3, Sec. 8.1
Sorptive rate; (seconds)	<1	
Non-volatile residue, NVR		IEST-RP-CC004.3, Sec. 7.1.1
In deionized water; (g/m <sup>2</sup> )	0.005	
In isopropyl alcohol; (g/m <sup>2</sup> )	0.008	
Specific ions		IEST-RP-CC004.3, Sec. 7.2.2
Sodium; (ppm)	0.040	
Chloride; (ppm)	0.048	
Particles, readily releasable		
Particles $\geq 0.5\mu\text{m}$ ; ( $\times 10^6/\text{m}^2$ )	6.17	IEST-RP-CC004.3, Sec. 6.1.3
Fibers $\geq 100\mu\text{m}$ ; ( $\times 10^3/\text{m}^2$ )	0.113	IEST-RP-CC004.3, Sec. 6.2.2

Packaging	EA/OB1	OB1/OB2	OB2/OB3	OB3/CS	EA/CS
LWLE0001	10	1	1	50	500
LWLE0002	10	1	1	36	360

EA = each; OB = outer bag; CS = case

#### Notes

- The data shown are typical values and should not be used as product specifications.
- Valid product comparisons may only be obtained through side-by-side testing in the same test facility, under similar conditions.
- Current and/or comparison data may be available. Please contact a Contec sales representative for details.

#### Test Methods

- CTM = Contec Test Method
- IEST-RP-CC004.3 = Evaluating Wiping Materials Used in Cleanroom and Other Controlled Environments, Institute of environmental Sciences and Technology, Rolling Meadows IL