

Amplitude™ Kappa™ Sterile LE Wipes

Amplitude™ Kappa™ Sterile LE Wipes are the first sterile low endotoxin nonwoven wiping product designed for the pharmaceutical, medical device and biotech industries. Made with Sontara® Iyocell/polyester blend fabric, these low endotoxin wipes have excellent sorbency and are packaged, gamma sterilized and validated sterile to a 10^{-6} Sterility Assurance Level.

The linear tear packaging allows for easy opening. Packaged in small quantities to minimize waste, these wipes are ideal for use in aseptic processing areas. Amplitude™ Kappa™ Sterile LE wipes meet the FDA standard for bacterial endotoxins using Limulus Amoebocyte Lysate (LAL) at the endotoxin limit of <20 EU/wipe

Amplitude Kappa Sterile LE wipes are validated per the AAMI/ISO 11137 Guidelines for the sterilization of medical devices. Validation reports are available from Contec upon request.



Applications

- Ideal for product wipe down and cleaning the exterior of equipment, and facilities cleaning
- Specifically designed for the biotech, pharmaceutical, and medical device industries
- Use for dry wiping and spill control
- Use in bio-safety cabinets, isolators and hoods
- ISO Class 5 (Grades A/B) environments compatible
- Ideal for use in aseptic processing areas

Amplitude™ Kappa™ Sterile LE Wipes

Sterile low endotoxin lyocell/polyester wipes

Amplitude™ Kappa™ Sterile LE wipes are the first sterile low endotoxin nonwoven wiping product designed for the pharmaceutical, medical device and biotech industries. Made with Sontara® lyocell/polyester blend fabric, these low endotoxin wipes are packaged, gamma sterilized and validated by Contec, Inc.

Available in 9 x 9" (23 x 23cm) and 12 x 12" (30.5 x 30.5cm) sizes and packaged in small quantities to minimize wipe waste, these wipes are ideal for use in aseptic processing areas. Amplitude™ Kappa™ Sterile LE wipes are validated per the AAMI/ISO 11137 Guidelines for the sterilization of medical devices. Validation reports are available from Contec upon request.

Amplitude™ Kappa™ Sterile LE wipes meet the FDA standard for bacterial endotoxins using Limulus Amoebocyte Lysate at the endotoxin limit of <20 EU/device.



Contec's innovative sterile packaging features a peelable outer bag and linear tear inner bag. Printed lot numbers on both bags ensure lot traceability.

PRODUCT FEATURES

Sterilized by Cobalt-60 Gamma Radiation. Amplitude Kappa Sterile LE wipes are irradiated to a minimum dose of 25.0 kGy.

Validated sterile to 10⁻⁶ SAL (Sterility Assurance Level). A certificate of sterility is included with each case of product.

Amplitude Kappa Sterile LE wipes are double packaged with printed lot numbers on both inner and outer bags, ensuring lot traceability.

Amplitude Kappa Sterile LE wipes have a high water and solvent sorbent capacity and rate.

Test results for the Amplitude Kappa Sterile LE wipes show low levels of particles and extractables.

Compatible with Class 5 Cleanroom environments, Amplitude Kappa Sterile LE wipes are ideal for many applications, including wiping articles prior to pass through, cleaning equipment surfaces and facilities cleaning.

TESTING

Extensive validation testing was conducted by Contec® and Sontara® before the initial release of Amplitude Kappa Sterile LE wipes:

CONTEC®

- Sterility validation and dose audits on finished product
- Endotoxin testing using LAL test method on finished product
- Bioburden testing on wipes during the manufacturing process

Sontara®

- Bioburden testing on process water and fabric
- Endotoxin testing on fabric

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P.O. Box 530 • Spartanburg, SC 29304 USA
 +1-864-503-8333 • fax: +1-864-503-8444
 Toll Free: 1-800-289-5762
 www.contecinc.com • e-mail: wipers@contecinc.com

Ordering Information

Part #	Description	Wipes/Bag	Inner Bags/ Outer Bag	Bags/Case
NWPZ0001	Amplitude Kappa Sterile LE Wipes, 9 x 9" (23 x 23cm)	25	4	10
NWPZ0002	Amplitude Kappa Sterile LE Wipes, 12 x 12" (30.5 x 30.5cm)	25	4	10



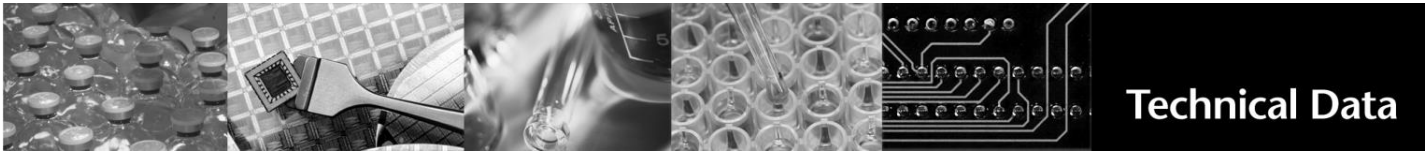
What are Pyrogens?

Pyrogens are fever-producing substances derived from the outer shell membranes of decaying bacteria. Bacterial endotoxins, from the outer membranes of gram-negative bacteria, are the most common pyrogens. Endotoxins are tested using a Limulus Amoebocyte Lysate (LAL) test method. The presence of pyrogens is a critical safety concern since these substances cannot be easily removed. Products contaminated with pyrogens can pose a life-threatening risk to patients. Use of nonpyrogenic sterile wipes during manufacturing reduces the potential for pyrogen contamination often observed in today's nonwoven wipes.

Amplitude Kappa Sterile LE wipes are the first sterile nonpyrogenic nonwoven wipe designed for the medical device, pharmaceutical and biotech industries.



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Amplitude™ Kappa™ Sterile LE Wipes

Sterile Lyocell/polyester Low Endotoxin nonwoven wipes

Description

Amplitude Kappa Sterile LE Wipes, formerly DuPont™ Sontara® Nonpyrogenic Wipes, features a spunlaced lyocell/polyester blend that incorporates maximum sorptive capacity, particle removal capability, and low levels of particulate and extractable contaminants. A unique manufacturing process gives this low endotoxin wipe the greatest level of intrinsic sorbency of any cleanroom compatible nonwoven wipe available. Validated sterile to a Sterility Assurance Level (SAL) of 10⁻⁶, per Association for the Advancement of Medical Instrumentation (AAMI) Guidelines, each batch of wipes has a guaranteed endotoxin level of less than 20 EU per device.

Technical Data

Wipe material	Lyocell/ Polyester	
Wipe Construction	Hydroentangled, aperatured	
Attribute; (units)	Value	Test Method
Basis weight; nominal (g/m ²)	61	Contec Method
Sorbency in water		
Intrinsic; (mL/g)	6.46	IEST-RP-CC004.3, Sec. 8.1
Extrinsic; (mL/m ²)	395	IEST-RP-CC004.3, Sec. 8.1
Sorptive rate; (seconds)	<1.0	
Non-volatile residue, NVR		IEST-RP-CC004.3, Sec. 7.1.2
In deionized water; (g/m ²)	0.024	
In isopropanol; (g/m ²)	0.011	
Specific ions		IEST-RP-CC004.3, Sec. 7.2.2
Sodium; (ppm)	13.66	
Chloride; (ppm)	12.46	
Particles, readily releasable		IEST-RP-CC004.2, Sec. 5.1
P ≥ 0.5µm; (x10 ⁶ /m ²)	16.3	
Fibers > 100µm; (x10 ³ /m ²)	22	IEST-RP-CC004.2, Sec. 5.2

Part Number	Description	EA/OB	OB/CS
NWPZ0001	Amplitude Kappa Sterile LE Wipes, 9" x 9" (23 x 23cm)	25	40
NWPZ0002	Amplitude Kappa Sterile LE Wipes, 12" x 12" (30 x 30cm)	25	40

EA = Each, OB = Outer Bag, CS = Case

Notes:

- 1) The information presented here is applicable to the part numbers shown above, as well as to any product containing the same materials and produced under the same conditions, regardless of product size or packaging configuration. Please contact a Contec sales representative for more details.
- 2) Data shown are typical values and should not be used as product specifications.
- 3) Valid product comparisons may only be obtained through side-by-side testing in the same test facility, under similar conditions.
- 4) Current and/or comparison data may be available. Please contact a Contec sales representative for details.

Revision date: 10/07/15
ETR 2975, 2976



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North America
P.O. Box 530
Spartanburg, SC 29304 USA
Phone: +1-864-503-8333
www.contecinc.com

Europe
Zl du Prat – RP 3707
56037 VANNES Cedex
FRANCE
+33 297 437 690

China
No.17 Longyun Road
Suzhou 215024
CHINA
+ 86-512-6274 4050