CONTEC®

Low Endotoxin Products for Critical Environments

www.contecinc.com

Contec® is a leading manufacturer of contamination control products for critical cleaning in manufacturing environments worldwide. Contec's cleanroom wipes, mops and disinfectants are used in various industries across the globe including biotechnology, pharmaceutical, medical device, healthcare and other critical life science applications.

Experienced

With more than twenty eight years of experience, we understand the unique cleaning and contamination control requirements of these highly regulated markets. Our sales and technical support teams are fully trained to assist customers in finding or creating a Contec product that best meets their needs. With experienced, long-established sales representatives all over the world, our customers benefit from personalised service and fast, efficient sample and order turnaround.

Global

Contec has established a cleanroom manufacturing facility and a distribution centre centre in Europe which allows us to locally support our European customers. Contec owns and operates further manufacturing facilities in South Carolina, USA, Suzhou China and Ashington UK. Contec has a team of technical specialists and sales representatives in Europe, North and South America, and Asia. These facilities and dedicated team members give Contec the ability to provide product and technical support to multi-national customers with global needs.

Committed to quality

We recognise our customers as the centre of our organisational structure. Our employees are committed to meeting each customer's specifications and exceeding each customer's expectations. We will achieve this through the periodic review and continuous improvement of all processes in our management system.

All manufacturing sites are currently certified to ISO 9001:2008, soon to be updated to ISO 9001:2015, which ensures customers of consistent quality products - from development to devliery. As a vertically integrated manufacturer, Contec controls more of the manufacturing process than any other supplier. We invite you to come and visit our manufacturing facilities and find out for yourselves.

Committed to customers

Let us help solve your cleaning challenges. Product samples, demonstrations and trials are always offered free-of-charge. We have regional technical specialists working with our professional sales staff who will come to your location and recommend the best product and practices for your needs. If necessary we can develop unique custom solutions to your problems.

CONTEC®

Low Endotoxin Range

A complete range of dry and presaturated wipes, alcohols and disinfectants with guaranteed low endotoxin limits.

With more than twenty eight years of experience, Contec has developed the most complete range of wipes and mopping products for the life science industry. Through years of continuous improvement, Contec has created processes which minimise and control bioburden allowing a broad range of products to be developed with low levels of endotoxins.

The use of low endotoxin products for cleaning and contamination control can help to minimise the risk of endotoxin contamination of a pharmaceutical product. Contec offers low endotoxin certified products, including dry and presaturated, knitted and nonwoven wipes, sterile 70% alcohols, and low residue disinfectants for the most critical applications. In addition to sterility, each batch is tested before release to ensure a guaranteed low level of endotoxin.

Contents

All Contec's Low Endotoxin products are highlighted with the purple LE symbol. All products in this catalogue have guaranteed low levels of endotoxin.

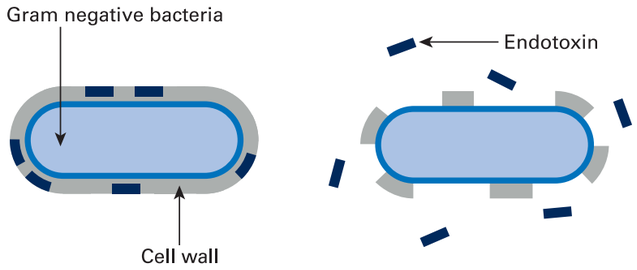
All Contec's validated sterile products are highlighted by a red 10^{-6} symbol. The products are validated sterile according to the "Association for the Advancement of Medical Instrumentation (AAMI) 11137 Guidelines" to a 10^{-6} Sterility Assurance Level.

"Unlike viable microbial contamination, pyrogens are difficult to remove and deactivate."

Endotoxin Control

The presence of pyrogens is a critical safety concern with 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 sterilisation techniques, pyrogens are difficult to remove and deactivate.

Pyrogens are fever-producing substances (from pyro the Greek word for fire) released from the outer membranes of decaying bacteria. Bacterial endotoxins, specifically from the outer membranes of gram negative bacteria, are the most common pharmaceutical pyrogens, so much so that the terms are often used interchangeably. Bacterial endotoxins are members of a class of phosolipids called lipopolysaccharides (LPS). The release of LPS from bacteria takes place after the cell death and bursting of the cell wall. Examples of endotoxin-releasing, gram-negative bacteria are *Escherichia coli, Pseudomonas aeruginosa, Enterobacter aerogenes and Klebsiella pneumoniae.*



Endotoxin Limits

The pyrogenic threshold for humans is approximately 5 EU per kg. This means that an intravenous or intramuscular administration of more than 5 EU/kg/hour can be expected to elicit a pyrogenic (fever-inducing) response. Intraspinal spaces have no clearance mechanism so the EU limit for intrathecal administrations is much more stringent. A limit of 0.2EU/KG/hr was set for products administered intrathecally. Also used is a more scientifically calculated intrathecal limit of 14 EU per day. These calculations are based on the assumption that the average person weighs 70kg. The limits for children and animals are even lower.

As well as injectable fluids, endotoxin limits are also set for medical devices, 20 EU/device for most medical devices except those in contact with cerebrospinal fluid which is 2.15EU per device.

The Ph Eur general monograph "Substances for pharmaceutical use (2034)" and individual monographs on substances for pharmaceutical use require compliance with the Bacterial Endotoxin Test when substances are used in the manufacture of parenteral preparations.

Sources of Endotoxin

There can be several sources of endotoxin in parenteral and medical device products. Usual sources are the water used either as the solvent or in the processing, packaging components, chemicals and raw materials or equipment used in the preparation of the product. Control of the microbiological and endotoxin levels in these areas can help keep endotoxin limits under their required limits for the finished product, i.e. the use of endotoxin-free glassware and implements, the use of water for injection or process water that has been treated to have less than 0.25 EU/ml and to use raw materials and chemicals from a reputable source with confirmed endotoxin limits.

Preventing Endotoxin Contamination

Endotoxins are very difficult to remove as they vary in molecular weight and are tolerant to changes in pH and temperature. Obviously, sterilisation is not the answer since endotoxins are not living organisms but are released from the decaying outer cell walls of gram-negative bacteria. The FDA Inspection Technical Guide states that:

"It is difficult to remove endotoxins from products once present. It is far better to keep finished products and components relatively endotoxin free rather than have to remove it once present."

Water for Injection (WFI) is used in the production of parenteral drugs and other critical products when endotoxin levels must be controlled. The limits for bacterial endotoxins in WFI are ≤ 0.25 EU/mL or ≤0.25 I.U./mL as stated in the USP Monograph on Water for Injection and the European Pharmacopoeia, Water for Injection Monograph, respectively.

There are no regulations for endotoxin levels in cleanroom wipes and products, however, convention is usually that low endotoxin products meet the requirement of <0.25 EU/mL or <20 EU/device. Products certified as low endotoxin are not required to use low endotoxin ingredients, but the final product must be tested for conformance to EP requirements for endotoxin levels. Finished products containing WFI have a component (water) that is low endotoxin, but for the finished product to be classified as low endotoxin, it must be batch tested to meet the stated limits to ensure all components of the product, packaging and manufacturing cycle have been controlled to produce a low endotoxin result.

Control of process water, raw materials and production equipment all contribute to prevent endotoxin contamination of the finished product throughout the process. The use of a complete range of low endotoxin contamination control products will prevent the addition of further bioburden or endotoxins into the manufacturing process and product contact areas.

The blood of the prehistoric horseshoe crab is used to carry out the Limulus Amebocyte Lysate (LAL) test for detection and quantification of bacterial endotoxin.

Contamination Control Consumables

The use of low endotoxin products for cleaning and contamination control can help to minimise the risk of endotoxin contamination of a pharmaceutical product.

Contec offers a full line of low endotoxin certified products, including presaturated wipes, dry knit and nonwoven wipes, and sterile 70% alcohols and low residue disinfectants, for the most critical applications. Each batch is tested before release to ensure a guaranteed low level of endotoxin.

Sterile 70% IPA or denatured ethanol, and a 6% hydrogen peroxide solution are all available with a guaranteed endotoxin limit of 0.25 EU/ml. To complement these, a range of dry wipes is also available with guaranteed low endotoxin levels. The cost effective Amplitude Kappa LE is a polyester/lyocell hydroentangled wipe, double bagged in small quantities with an endotoxin limit of 20 EU per wipe. Sterile Polynit Heatseal Low Endotoxin Wipes, made from 100% knitted polyester with sealed edges have an endotoxin limit of 1 EU per wipe. These wipes are triple bagged and also have very low levels of particles and fibres.

For greater convenience, presaturated wipes with 70% IPA could be used. Knitted polyester or melt blown polypropylene pouch wipes are available, depending on the low levels of particles and fibres that are also required.

All of Contec's low endotoxin contamination control consumables are batch tested using the Limulus Amebocyte Lysate test for quantification of endotoxin levels.

"The use of low endotoxin products for cleaning and contamination control can help to minimise the risk of endotoxin contamination."

PROSAT *Sterile* Knitted Polyester Wipes

100% knitted polyester wipes presaturated with 70% IPA

High quality knitted polyester wipe with a guaranteed endotoxin level of <1EU/wipe.

Product Information

PROSAT *Sterile* Low Endotoxin Wipes are manufactured from Polynit Heatseal, 100% knitted polyester presaturated with a blend of 70% IPA and 30% Water for Injection (WFI). Each batch is tested before release and low endotoxin certified to less than <1EU/wipe.

Polynit Heatseal is a 140gsm no-run interlock knit 100% polyester wipe with sealed edges. This sealed edge wipe produces very low levels of particles and fibres and is ideal for use on product contact surfaces. Each resealable pouch contains a small number of wipes, eliminating any waste at the end of a session. PSWE0001 and PSWE0003 are triple bagged for easy entry into the sterile suite.

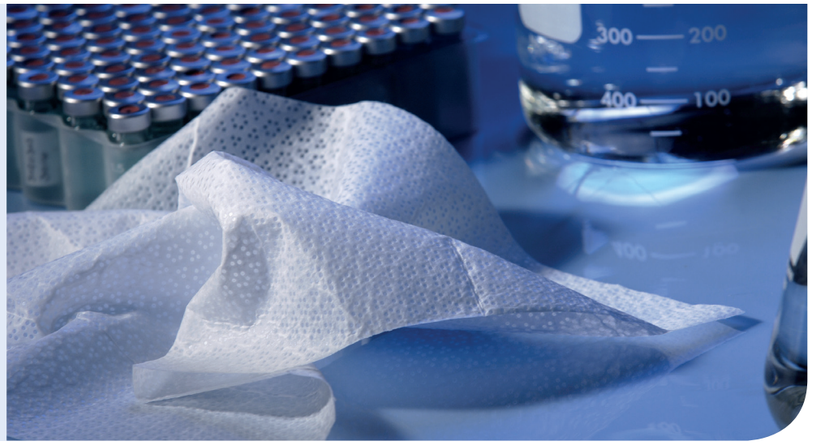
Presaturated wipes provide many benefits including solvent control, reduced Volatile Organic Compounds (VOC's) and increased process control and repeatability. PROSAT Sterile Low Endotoxin Wipes are validated sterile and ideal for use in aseptic suites and the most critical pharmaceutical cleanrooms.

Part No.	Description	Size	Quantity
PSWE0001	PROSAT *Sterile* Polynit Heatseal LE Wipes with 70% IPA and 30% WFI	230 x 230mm	10 wipes per pouch
PSWE0002	PROSAT *Sterile* Polynit Heatseal LE Wipes with 70% IPA and 30% WFI Flat stacked, double bagged	300 x 300mm	30 wipes per pouch
PSWE0003	PROSAT *Sterile* Polynit Heatseal LE Wipes with 70% IPA and 30% WFI	300 x 300mm	10 wipes per pouch

PROSAT *Sterile* Nonwoven Wipes

Nonwoven wipes presaturated with 70% IPA

A cost effective non woven wipe with a guaranteed low level of endotoxins.



Product Information

Contec's PROSAT *Sterile* Polypropylene Low Endotoxin wipes are presaturated with 70% USP Grade IPA and 30% Deionized Water. The meltblown polypropylene wipes provide a consistent release of solvent, making them ideal for laying down a film of disinfectant in critical environments.

Each batch is tested before release and low endotoxin certified to <20 EU/wipe, eliminating the risk of introducing endotoxins and other contaminants into product contact areas.

The resealable pouch and low number of wipes per pouch reduces waste. The use of a presaturated wipe helps control solvent usage and reduces VOC's. PROSAT *Sterile* Polypropylene Low Endotoxin Wipes are validated sterile so ideal for Grade A and B cleanrooms. Double bagged in polyethylene the pouches are easy to transfer into the controlled environment.

Part No.	Description	Size	Quantity
PS-911LE	PROSAT *Sterile* Polypropylene LE Wipes with 70% IPA and 30% DI water	230 x 280mm	30 wipes per pouch

Contec *Sterile* Polyester Wipes

Knitted polyester low endotoxin wipes with sealed edges

100% knitted polyester wipes with sealed edges and certified endotoxin level of <1 EU/wipe.

Product Information

Polynit Heatseal Low Endotoxin Wipes are manufactured from high quality 100% knitted polyester fabric with sealed edges and produce low levels of particles and fibres. The polyester fabric offers the widest range of solvent compatibility. Each batch is tested before release and low endotoxin certified to <1 EU/wipe.

The wipes are half-folded and triple packaged in linear tear outer bags for ease of transfer into ISO Class 5 (Grades A/B) 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. Polynit Heatseal Low Endotoxin Wipes are validated sterile and ideal for use in product contact areas.

Polynit Heatseal Low Endotoxin Wipes are validated sterile and ideal for use in product contact areas, in conjunction with a low endotoxin 70% alcohol solution.

Part No.	Description	Size	Quantity
LWLE0001	Sterile Polynit Heatseal LE Wipes	230 x 230mm	10 wipes per bag
LWLE0002	Sterile Polynit Heatseal LE Wipes	300 x 300mm	10 wipes per bag

Contec *Sterile* Nonwoven Wipes

Dry nonwoven low endotoxin wipes with good sorbency

“ Packaged in smaller quantities - ideal for use in aseptic processing areas.”

Sterile Amplitude Kappa LE Wipes are made from a special blend of lyocell and polyester fabric. These low endotoxin wipes have excellent sorbency and are validated sterile. Sterile Amplitude Kappa LE Wipes are batch tested and low endotoxin certified to <20 EU/ wipe.

The packaging allows for easy opening even when wearing gloves and the small quantities per pack minimise the possibility of any wastage. These wipes are ideal for use in aseptic processing areas, areas when increased sorbency is needed or a textured surface is required for efficient cleaning and particle removal. The wipes are also highly suitable for spill control and wiping-to-dry.

Product Information

Part No.	Description	Size	Quantity
NWPZ0001	Sterile Amplitude Kappa LE Wipes	230 x 230mm	25 wipes per bag
NWPZ0002	Sterile Amplitude Kappa LE Wipes	300 x 300mm	25 wipes per bag

Contec *Sterile* Alcohols

70% IPA or denatured ethanol blended with WFI

Sterility and endotoxin levels are tested and certified for every batch.

Product Information

Contec *Sterile* alcohols are a blend of 70% v/v Isopropanol or denatured ethanol with 30% water for injection or purified water. The alcohol blend is 0.2 micron filtered, filled and bagged in a Grade C (ISO Class 7) cleanroom. This clean manufacture coupled with water for injection or purified water means the alcohol blend is guaranteed to have an endotoxin level of less than 0.25EU / ml.

Contec's ethanol is denatured only with IPA creating a very low residue product. Contec sterile alcohol is provided sterile by gamma irradiation using a validated process at no less than 25 kGy. Each bottle is individually double or tripled bagged, for ease of entry into high grade areas. The linear tear bags are easy to open even when wearing gloves.

Supplied as 0.5L or 1L trigger sprays fitted with a protected system, which ensures sterility of the bottle contents througout use, or 5L capped containers for larger areas. Sterility and endotoxin levels are tested and certified for every batch.

Part No.	Description	Quantity
SBT0570IW	Contec *Sterile* 70% IPA in WFI 0.5L Trigger Spray	8 x 0.5L
SBT170IW	Contec *Sterile* 70% IPA in WFI 1L Trigger Spray	6 x 1L
SBC570I	Contec *Sterile* 70% IPA in purified water 5L Capped 2 x 5L	2 x 5L
SBT0570DEW	Contec *Sterile* 70% Denatured Ethanol in WFI 0.5L Trigger Spray	8 x 0.5L
SBT170DEW	Contec *Sterile* 70% Denatured Ethanol in WFI 1L Trigger Spray	6 x 1L
SBC570DE	Contec *Sterile* 70% Denatured Ethanol in purified water 5L Capped	2 x 5L

Contec *Sterile* HydroPure

Sterile stabilised 6% hydrogen peroxide solution

Blend of hydrogen peroxide and WFI with a guaranteed endotoxin level of 0.25 EU/ml.

Product Information

Contec *Sterile* HydroPure is a blend of 6% hydrogen peroxide and water for injection.

Efficacious against bacteria, fungi, moulds, yeasts and spores, Contec HydroPure leaves little to no residue and has a guaranteed endotoxin level of less than 0.25 EU/ml making it ideal for use in product contact areas.

Hydrogen peroxide is not classed as corrosive and can be used safely in all areas of a cleanroom.

Contec HydroPure is available sterile in a protected 1L trigger spray. The product is 0.2µm sterile filtered and filled into pre-irradiated containers under Grade A unidirectional airflow and bagged in a Grade C cleanroom.

Certificates of analysis are available for each batch. Each bottle of Contec HydroPure is triple bagged allowing for ease of entry into controlled environments. It is easy to open even when wearing gloves.

Contec HydroPure has been tested against EN1276, EN1650, EN13704, EN13697. It is bactericidal in 5 mins with fungicidal and sporicidal efficacy in 15 mins.

Part No.	Description	Quantity
SBT16HPW	Contec *Sterile* HydroPure 1L Trigger Spray	6 x 1L

Contec® cleaning and disinfecting products are available throughout the world. Sales and technical support representatives are conveniently located across Europe, Asia, and North and South America. Visit our web site to find a representative in your area and to learn more about our products for critical environments.

Presaturated Wipes
Mopping Systems
Disinfectants
Spill Control Products
Knitted Wipes
Sterile Products
Sponges
Nonwoven Wipes
Swabs

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For more information or to request a sample from the Contec low endotoxin range, please go to vwr.com/cleanroom or contact your local VWR account manager.

VWR® We Enable Science