

VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



DECON-CLEAN® Wipe

Residue Remover and Cleaner Pre-Saturated 100% Polyester Wipe



Product Overview

DECON-CLEAN® Wipes are ready-to-use and saturated with VAI®'s **DECON-CLEAN** residue remover and cleaner solution. **DECON-CLEAN** Wipes are designed to remove residue from disinfecting agents left behind on any critical surface that requires cleaning. These wipes can be used in both aseptic and non-aseptic wipe downs of filling and packaging machinery, and on a multitude of surfaces including stainless steel, lexan, polycarbonate, and glass. Removing residues returns the surface to original form and assures that future decontamination will be able to penetrate to the surface. Pre-saturated wipers, including **DECON-CLEAN** Wipes, can prevent the overuse of chemicals and reduce costs. **DECON-CLEAN** Wipes are available sterile in a standard 12"x12" (30.5 cm x 30.5 cm) size.

DECON-CLEAN wipes are filled in ISO 5 (Grade A/B, Former Class 100), filtered, and subsequently terminally sterilized to 10⁻⁶ sterility assurance level. Individual lots are sterility tested according to current USP compendium, are completely traceable, and completely validated for sterility and shelf life. **DECON-CLEAN Wipes** are delivered each time with lot specific Certificate of Analysis, Certificate of Irradiation, Certificate of Sterility, and Certificate of Conformance.

The material used in our **DECON-CLEAN Wipes** is a 100% continuous knit polyester filament that has been specifically designed to be exceptionally clean and absorbent. Particulates, residues, and foreign matter is effectively entrapped in the webbing of the material. The knit construction and pattern has been developed to ensure the greatest product integrity and cleaning performance while offering high resistance to abrasion and picking.

FocusEdge cutting technology is the standard that VAI uses to cut their wipes. This cutting method does not heat the yarn bundles as high as lasers, therefore, eliminating the small plastic balls that form on the end of every yarn strand. Due to the wipe's sealed edges, shedding is minimal during wipe downs or general use, therefore, reducing particulates in controlled environments. After cutting, the wipes are then laundered in ISO Class 4 conditions to ensure cleanliness.

VAI's **DECON-CLEAN Wipes** are packaged in an opaque, ported, peel and reseal style bag. The addition of a user-friendly peel and reseal label, that covers the opening of the bag, allows continued use after opening. Each sterile wiper bag is double bag packaged and available in our ABCD Cleanroom Introduction System[®] for easy introduction into the core or other critical environments.

Product Uses

- Remove residues left behind from disinfecting agents
- Return the surface to its original form for future disinfection
- General wiping in aseptic or non-aseptic environments
- Wipe downs on filling and packaging machinery
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning
- To prevent overuse of chemicals when compared to using trigger sprayers or gallon pour



Quality and Manufacturing

- Wipe material laundered in ISO 4 (Grade A/B, Former Class 10)
- **DECON-CLEAN Wipe** residue remover and cleaner solution is filtered and formulated with Water for Injection (WFI)
- Filled in ISO 5 (Grade A/B, Former Class 100)
- Cut using FocusEdge cutting technology
- Gamma irradiated at 10⁻⁶ SAL
- Lot sterility tested according to current USP Compendium
- Completely lot traceable
- Completely validated for sterility and shelf life

Features and Benefits

- ISO 5 (Grade A/B, Former Class 100) Cleanliness
- Each sterile bag is double bagged in easy tear bags
- Quadruple bagged via the ABCD Cleanroom Introduction System[®]
- Individually labeled with lot number and expiration
- Packaged in an opaque bag
- Peel and reseal label for continued use after opening
- Removes residues left behind from disinfecting agents that build up on surfaces overtime
- Helps return the surface to its original form for future disinfecting
- For use on multiple surfaces
- Wipes folded for easy removal
- 100% synthetic filament polyester constructed in a continuous knit that minimizes fiber and particulate release
- Material is exceptionally clean and absorbent
- Resistance to abrasion and picking
- FocusEdge allows for minimal shedding via sealed edges
- Standard 12"x12" (30.5 cm x 30.5 cm) size
- Ready-to-use
- Delivered with lot specific Certificate of Analysis, Certificate of Sterility, Certificate of Irradiation, and Certificate of Conformance



Ported bag for filling



Peel & Reseal Label



Peel & Reseal in Use



ABCD Cleanroom Introduction System®

The ABCD Cleanroom Introduction System is a packaging system that allows operators/users to take the package through each level of classified areas by simply removing one bag at a time. Each bag acts as barrier protecting the finished product from becoming a carrier of viable and non-viable contamination. This prevents the need to decontaminate each outer bag prior to entering a cleaner area. In this packaging system, sterilized groups of containers are contained in two outer bags and after each are removed individual containers are each additionally contained in two easy tear bags.

Material Specifications

DECON-CLEAN Wipe – Laundered Polyester Wipe		
Certificate of Conformance	Specification	
Material:	100% Polyester	
Material Description:	Laundered Polyester Wipe	
Color:	White	
Classification Compatibility:	ISO Class 5 (Former Class 100)	
Construction:	Continuous Filament Knitted Construction	
Dimension:	12"x12" (30.5 cm x 30.5 cm)	
Thickness:	0.56 – 0.64 mm	
Sorption Capacity:	$>= 270 \text{ mL/m}^2$	
Particles:	<4.5x10 ⁶ particles/m ²	
Fibers @ 100 um/m ² :	63, 1.0 IEST-RP-CC004.3, SEC 6.1.3/6.2.2	

*Treatable surface area not to exceed 1 sq. meter



100% Polyester Wiper Substrate



Chemical Specifications

DECON-CLEAN Wipe – Residue Remover and Cleaner		
Certificate of Analysis	Specifications	
pH:	8.0 - 10.5	
Appearance:	Clear	
Non-Volatile Residue:	<150 mg	
Expiration Period:	2 Years	

Ordering Information

DECON-CLEAN Wipe – Residue Remover and Cleaner			
Part number	Description	Qty/Case	
VEL14-12X12-S-4002	DECON-CLEAN Wipe, 20 wipes/bag, 10 bags/case, Sterile	200	



VEL14-12X12-S-4002



PRODUCT LABELING

DECON-CLEAN[®] Wipe Residue Remover and Cleaner

(Any specific product label is available upon request.)



DECON-CLEAN Wipe



DECON-CLEAN® Wipe

Pharmaceutical Clean Room Formula

Active Ingredients

(**elemental phosphate less than 0.02% by weight of concentrate before use dilution)

Net Contents: 20 Wipes SDS No: VEL-042 Reorder#: VEL14-12X12-S-4002

Made in USA.

Container and Product Sterilized and Distributed By: Veltek Associates, Inc. 15 Lee Blvd. Malvern, PA 19355-1234 USA Tel: 1-610-644-8335 Fax: 1-610-644-8336 www.sterile.com

Veltek Associates, Inc. Postbus 1062 8200 BB Lelystad, Nederland Tel: +800-00888700 Fax: 1-610-644-8336 www.sterile.com

In Canada: Distributed By: Canada Clean Room (CCR) <u>www.ccrkanata.com</u>

Residue Remove. Fragrance Free. For Industrial Use Only.

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals. Do not get in eyes, on skin or on clothing. Harmful if swallowed. Wear goggles or face shield and rubber gloves when handling. Avoid contamination of food.

FIRST AID

EYES: Flush thoroughly with water for at least 15 minutes. **SKIN:** Wash affected area with soap and water. **INGESTION:** DO NOT INDUCE VOMITING. Call a Poison Control Center Immediately. **INHALATION:** Move to fresh air, give oxygen to exposed person if necessary.

RECOMMENDATIONS FOR USE

Wear chemical resistant gloves and safety glasses. Remove one or two wipes at a time. Close the package. Wipe article thoroughly. Discard after use.

EMERGENCIES: For Spill/Exposure Emergency Response Service from the USA in English, French and Spanish (and 23 other languages), call CARECHEM24 toll free at 1-215-207-0061, 1-866-928-0789, or 1-800-579-7421. For Canada toll free: 1-800-579-7421. For Mexico: +52-55-5004-8763. For Arabic, Middle East, Africa: +44-1235-239671. For Chinese: +86-10-5100-3039. For Europe in English (and 23 other European languages): +44-1235-239670. For Australia toll free: +61-2-8014-4558. For Hindi: 000-800-100-7479.



Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet SDS# VEL-042
- Product Validation
- Sample lot specific documentation packages including Certificates of Irradiation, Certificates of Sterility, Certificates of Conformance and Certificates of Analysis



VAI®'s Wiper Family

Veltek Associates, Inc. *Disposable Products Manufacturing Division's* capabilities include sterile disposable garments, sterile disposable face masks, dry wipers, sterile wipers, custom cleanroom documentation, sterile synthetic writing substrate, and a HEPA filtered cleanroom printer. DPMD has responded and met demands of professionals in the industry since 1985. Our manufacturing capabilities assure that we will be able to meet all requests and fulfill all of our customer's needs. All DPMD products are processed and packaged in cleanroom facilities from beginning to end and subsequently gamma irradiated or aseptically filled in order assure sterility. For more information call 610-644-8335, email sales@sterile.com or visit our website at www.sterile.com.

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