

VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



Process2Wipe® IPA70

70% USP Isopropyl Alcohol and 30% Water for Injection Pre-Saturated 9x9 Polyester Non-Woven Wipe



Product Overview

Process2Wipe[®] IPA70 wipes are ready-to-use and saturated with VAI[®]'s low endotoxin DECON-AHOL WFI[®] Formula, a 70% USP Isopropyl Alcohol formulated with 30% Water for Injection. These wipes can be used in both aseptic and non-aseptic wipe downs of filling and packaging machinery, stainless steel surfaces, lexan, polycarbonate, glass, and any critical surface that requires cleaning. Pre-saturated wipers, including **Process2Wipe**, can prevent the overuse of chemicals and reduce costs. **Process2Wipe** is available sterile in a standard 9"x9" (23 cm x 23 cm) size.

Process2Wipe wipes are filled in ISO 5 (Grade A/B, Former Class 100), filtered at 0.2 microns, 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. **Process2Wipe** wipes are delivered each time with lot specific Certificate of Analysis, LAL Test Report, Certificate of Irradiation, Certificate of Sterility, and Certificate of Conformance.

The material used in our **Process2Wipe** is a white, non-woven 100% polyester material that has low shedding characteristics and is manufactured to be clean and absorbent by minimizing fiber and particulate release. VAI's Process2Wipe is packaged in an opaque, ported, peel and reseal style bag with 50 wipers per bag. The peel and reseal style bag allows for 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 and other critical environments.

Product Uses

- Aseptic or non-aseptic environments
- Wipe downs on filling and packaging machinery
- Spill control
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning
- To prevent overuse of Isopropyl Alcohol when compared to using trigger sprayers or gallon pour
- General wiping and contamination control

Ouality and Manufacturing

- Filled in ISO 5 (Grade A/B, Former Class 100)
- 70% USP IPA formulated with 30% USP Water for Injection is filtered at 0.2 microns
- Gamma irradiated at 10⁻⁶ SAL
- Lot sterility tested according to current USP Compendium
- Completely lot traceable



Peel & Reseal Label



Features and Benefits

- Each sterile bag is double bagged in easy tear bags
- Quadruple bagged via the ABCD Cleanroom Introduction System[®]
- Packaged in an opaque bag
- Peel and reseal label for continued use after opening
- Individually labeled with lot number and expiration
- Reduced VOC's
- Low endotoxins
- For use on multiple surfaces
- Wipes folded for easy removal
- 100% polyester non-woven material designed to be clean and absorbent
- Material has low shedding characteristics
- 9"x9" (23 cm x 23 cm) size
- Ready-to-use
- Delivered with lot specific Certificate of Sterility, Certificate of Irradiation, Certificate of Analysis, LAL Test Report, and Certificate of Conformance

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

Process2Wipe – Hydroentangled Polyester Non-Woven*		
Certificate of Conformance	Values**	
Material:	100% Polyester	
Material Description:	Hydroentangled Polyester Non-Woven	
Color:	White	
Classification Compatibility:	ISO Class 5 (Former Class 100)	
Construction:	Non-woven	
Dimension:	9"x9" (23 cm x 23 cm)	
Thickness:	0.51 mm	
Basis Weight:	2.0 oz/sq yard	
Sorption Capacity:	339 mL/m ²	



Particles:	12 mm/m ² (@ 0.5 micron)
Fibers (via Biaxial Shake):	8710/ m ² (@ 100 microns)

*Treatable surface area not to exceed 1 sq. meter

** The test results listed above represent typical values obtained and are not product specifications

Chemical Specifications

Process2Wipe – 70% USP Isopropyl Alcohol 30% Water for Injection		
Certificate of Analysis	Specifications	
Appearance:	Clear Colorless	
Assay Test:	68.0-72.0%	
Acidity:	= 1.0 mL</td	
Nonvolatile Residue:	< 5.0 mg	
Specific gravity @ 20 degrees C:	0.872-0.883	
Fill Level:	650 mL	
Expiration Period:	2 Years	

Ordering Information

Process2Wipe – 70% USP Isopropyl Alcohol 30% Water for Injection			
Part number	Description	Qty/Case	
VEL12-9X9-S-3032	Process2Wipe IPA 70, Peel and Reseal Packaging, 50 wipes/bag, Sterile	1000	



VEL12-9X9-S-3032



PRODUCT LABELING

Process2Wipe[®] 70% USP Isopropyl Alcohol and 30% Water for Injection

(Any specific product label is available upon request.)



Alcohol Wipes Family





IPA 70 Sterile

Contains: 70% USP Isopropyl Alcohol 30% USP Water for Injection

Filtered at 0.2 um – Gamma irradiated at 10^{-6} SAL .

Made in USA.



KEEP OUT OF REACH OF CHILDREN.

DANGER.

Flammable liquid and vapor. Contains Alcohol – Eye Irritant. If product comes in contact with eyes, rinse promptly and thoroughly with water. If irritation persists, seek medical assistance.

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.

Container and Product Packaged 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

Contents: 9X9 wipes, 50 pack, Quan/Case: 1000. Reorder# VEL12-9X9-S-3032 Sterile

HAZARD STATEMENTS DANGER.

See Safety Data Sheet and/or leaflet for additional product information.



Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet SDS# VEL-038
- Sample lot specific documentation packages including Certificates of Irradiation, Certificates of Sterility, Certificates of Conformance, LAL Test Reports, 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.

Patents: www.sterile.com/patents