

VELTEK ASSOCIATES, INC.

# TECHNICAL DATA FILES



# STER-AHOL® Wipe

70% Denatured Ethanol and 30% Water for Injection Individually Packaged and Pre-Saturated 100% Polyester Wipe



#### **Product Overview**

The **STER-AHOL**® **Wipe** is a ready-to-use, individually packaged, and saturated wipe with VAI®'s 70% USP Denatured Ethanol and 30% Water for Injection **STER-AHOL**® WFI Formula. The **STER-AHOL Wipe** has been specifically designed for operations that require the use of an individually packaged and sterile EtOH wipe. 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 **STER-AHOL Wipe**, can prevent the overuse of chemicals and reduce costs. The **STER-AHOL Wipe** is available sterile in a standard 12"x12" (30.5 cm x 30.5 cm) size.

The **STER-AHOL Wipe** is filled in ISO 5 (Grade A/B, Former Class 100), filtered at 0.2 microns, and subsequently terminally sterilized to 10<sup>-6</sup> sterility assurance level. Individual lots are lot sterility tested according to current USP compendium, are completely traceable, and completely validated for sterility and shelf life. **STER-AHOL 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 **STER-AHOL Wipe** 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 **STER-AHOL Wipe** is packaged in an opaque, ported, and easy-tear style bag. Each wiper is individually bagged and packed in two liner bags for easy introduction into the core or other critical environments.

#### **Product Uses**

- Aseptic or non-aseptic environments
- Wipe downs on filling and packing machinery
- Spill control
- On lexan, glass, polycarbonate, stainless steel or any other critical surface that requires cleaning
- In operations that require an individually bagged denatured ethanol wiper
- To prevent overuse of EtOH when compared to using trigger sprayers or gallon pour



### **Quality and Manufacturing**

- Wipe material laundered in ISO 4 (Grade A/B, Former Class 10)
- 70% Denatured Ethanol and 30% Water for Injection solution is filtered at 0.2 microns
- Filled in ISO 5 (Grade A/B, Former Class 100)
- Cut using FocusEdge cutting technology
- Gamma irradiated to 10<sup>-6</sup> 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
- Individually labeled with lot number and expiration
- Folded for easy removal and individually bagged with two liner bags
- Packaged in an opaque, easy-tear style bag
- For use on multiple surfaces
- Ready-to-use
- 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
- Available in a 12"x12" (30.5 cm x 30.5 cm) size
- Delivered with lot specific Certificate of Analysis, Certificate of Irradiation, Certificate of Sterility, and Certificate of Conformance



100% Polyester Wiper Substrate

### **Chemical Specifications**

STER-AHOL Wipe – 70% Denatured Ethanol and 30% Water for Injection		
Certificate of Analysis	Specifications	
Appearance:	Clear	
Assay:	68.0 – 72.0%	
Nonvolatile Residue:	<5.0 mg	
Specific Gravity @ 20 Degrees C:	0.882 - 0.892	
Expiration Period:	2 years	



# **Material Specifications**

STER-AHOL Wipe – Laundered Polyester Wipe		
Certificate of Conformance	Specifications	
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 mL/m <sup>2</sup>	
Particles:	<4.5x10 <sup>6</sup> particles/m <sup>2</sup>	
Fibers @ 100 um/m <sup>2</sup> :	63, 1.0 IEST-RP-CC004.3, SEC 6.1.3/6.2.2	

<sup>\*</sup>Treatable surface area not to exceed 1 sq. meter

# **Ordering Information**

STER-AHOL Wipe – 70% Denatured Ethanol and 30% Water for Injection		
Part number	Description	Qty/Case
VEL6-12X12-S-2320	STER-AHOL® Wipe, Individually Bagged, Sterile	100



VEL6-12X12-S-2320



# PRODUCT LABELING

# STER-AHOL® Wipe 70% Denatured Ethanol and 30% Water for Injection

(Any specific product label is available upon request.)



Alcohol Wipes Family



## **ETHANOL-WIPE Sterile**

# 70% Denatured Ethanol Saturated Cleanroom Wipe

#### **Ingredients:**

Ethyl Alcohol	63.4%
Methyl Alcohol	3.2%
Isopropyl Alcohol	3.4%
Purified Water, USP	3.4%
Total	100%

# DANGER – FLAMMABLE KEEP OUT OF REACH OF CHILDREN





KEEP FROM HEAT OF OPEN FLAME, DO NOT STORE ABOVE 120°F.

### **FIRST AID**

**Eye Contact:** Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present. Get medical attention if irritation persists after washing. **Skin Contact:** Wash skin with soap and water. Get medical attention if irritation develops and persists. **Inhalation:** Move into fresh air and keep at rest. If breathing stops, provide artificial respiration. Get medical attention if any discomfort continues.

### HAZARD STATEMENTS DANGER

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

**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.

SDS# VEL-039

Made in USA.

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### **Additional Documentation**

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet SDS# VEL-039
- Product Validation
- Sample lot specific documentation packages including Certificates of Sterility, Certificates of Irradiation, Certificate of Analysis, and Certificate of Conformance



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 <a href="mailto:sales@sterile.com">sales@sterile.com</a> or visit our website at <a href="www.sterile.com">www.sterile.com</a>.

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