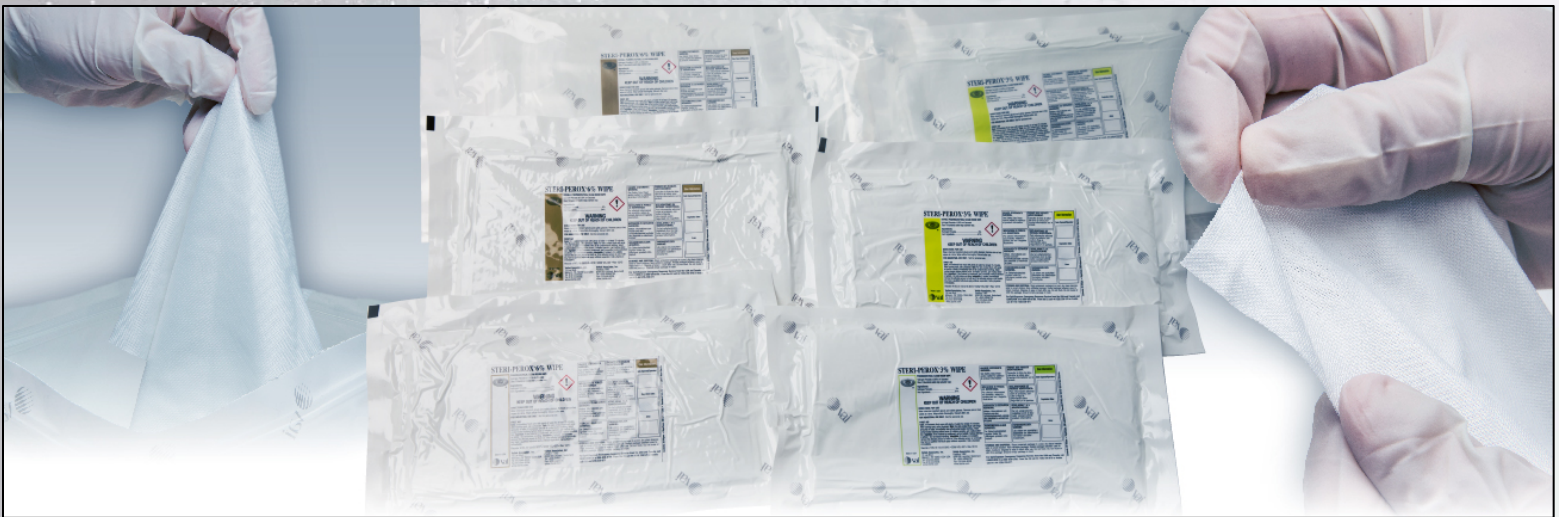




VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



STERI-PEROX[®] Wipe 3% & 6%

Hydrogen Peroxide and Water for Injection Solution

Pre-Saturated 100% Polyester Wipe

Product Overview

STERI-PEROX® Wipes are saturated with a ready-to-use 3% or 6% concentration of hydrogen peroxide solution formulated with 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. Ideal use is in broad or intricate locations where the need to reduce possible VOC's is required. Pre-saturated wipers, including **STERI-PEROX Wipes**, can prevent the overuse of chemicals and reduce costs. **STERI-PEROX Wipes** are available in a standard 12"x12" (30.5 cm x 30.5 cm) size and either sterile or non-sterile.

STERI-PEROX Wipes are manufactured via aseptic fill at 0.2 microns into gamma irradiated sterile components in ISO 5 (Grade A/B, Former Class 100). Individual lots are lot sterility tested according to current USP compendium, are completely traceable, and completely validated for sterility and shelf life. **STERI-PEROX Wipes** are delivered each time with lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Conformance.

The material used in our **STERI-PEROX 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 **STERI-PEROX 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

- 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
- To reduce VOC's
- To prevent overuse of hydrogen peroxide when compared to using trigger sprayers or gallon pour

Quality and Manufacturing

- Wipe material laundered in ISO 4 (Grade A/B, Former Class 10)
- Hydrogen peroxide solution is filtered at 0.2 microns
- Filled in ISO 5 (Grade A/B, Former Class 100)
- Formulated with Water for Injection
- Cut using FocusEdge cutting technology
- Aseptically filled into sterile components via gamma irradiation at 10^{-6} SAL
- Lot sterility tested according to current USP Compendium
- Completely lot traceable
- Completely validated for sterility and shelf life



Ported Bag for Aseptic Filling

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®
- Packaged in an opaque bag
- Peel and reseal label for continued use after opening
- Individually labeled with lot number and expiration
- Two concentrations: 3% or 6% to fit your specific needs
- Reduced VOC's
- For use on multiple surfaces
- Ready-to-use
- 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" size (30.5 cm x 30.5 cm)
- Delivered with lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Conformance



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

STERI-PEROX 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 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

STERI-PEROX Wipe – Hydrogen Peroxide and Water for Injection	
Certificate of Analysis	Specifications
Assay 3%:	2.5% - 3.5%
Assay 6%:	6.0% - 6.9%
Acidity 3%:	<5.5 mL
Acidity 6%:	<5.5 mL
Barium:	No turbidity
Heavy Metals (as Pb):	<5 ppm
Nonvolatile Residue:	<30 mg
Perservative:	<50 mg
Expiration Period:	2 Years

Ordering Information

STERI-PEROX Wipe – Hydrogen Peroxide and Water for Injection		
Part number	Description	Qty/Case
VEL10-12X12-3017	STERI-PEROX® Wipe 6%, 20 wipes/bag, 10 bags/case, Non-Sterile	200
VEL10-12X12-S-3016	STERI-PEROX Wipe 6%, 20 wipes/bag, 10 bags/case, Sterile	200
VEL10-12X12-3015	STERI-PEROX Wipe 3%, 20 wipes/bag, 10 bags/case, Non-Sterile	200
VEL10-12X12-S-3014	STERI-PEROX Wipe 3%, 20 wipes/bag, 10 bags/case, Sterile	200



VEL10-12X12-S-3014



VEL10-12X12-3017

PRODUCT LABELING

STERI-PEROX® Wipe 3% & 6%

Hydrogen Peroxide and Water for Injection Solution

(Any specific product label is available upon request.)



STERI-PEROX Wipe Family

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355-1234

Tel: 610-644-8335 Fax: 610-644-8335 www.sterile.com Rev: 18Feb2019



STERI-PEROX® Wipe 3% and 6%
Sterile Pharmaceutical Cleanroom Wipe
Class 10 Laundered Sealed Edge Polyester Wipe

STERI-PEROX Wipe 3%

Hydrogen Peroxide at 3.00% Vol/Vol. in USP Water for Injection

Ingredients 3%:
 Hydrogen Peroxide3.0%
 Inert Ingredients.....97.0%
Total100%
 SDS# VEL-037-3

STERI-PEROX Wipe 6%

Hydrogen Peroxide at 6.00% Vol/Vol. in USP Water for Injection

Ingredients 6%:
 Hydrogen Peroxide6.0%
 Inert Ingredients.....94.0%
Total100%
 SDS# VEL-037-6

KEEP OUT OF THE REACH OF CHILDREN
WARNING



FOR INDUSTRIAL USE ONLY. Not for personal 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.

Made in USA.

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

Directions for Use

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

FIRST AID

EYES: Immediately flush eyes with plenty of water for at least 15 minutes. After flushing eyes, call a physician. **SKIN:** For skin contact flush with large amounts of water. Immediately take off all contaminated clothing. Wash contaminated clothing before reuse. If irritation persists, get medical attention. **INGESTION:** If the material is swallowed, get immediate medical attention or advice – Do not induce vomiting. **INHALATION:** If inhaled, immediately remove the affected person to fresh air. If the affected person is not breathing, have a qualified individual apply artificial respiration. Call a physician immediately.

HAZARD STATEMENTS WARNING

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

STORAGE AND DISPOSAL

Store unopened package in a cool, dry place inaccessible to small children. Non-refillable package. Reseal packaging between uses to retain moisture. Dispose of wipe in trash after use. Do not flush. Do not reuse or refill this package. Discard empty package in trash.

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet
 - **STERI-PEROX Wipe 3%** – SDS# VEL-037-3
 - **STERI-PEROX Wipe 6%** – SDS# VEL-037-6
- Product Validation
- Sample lot specific documentation packages including Certificates of Sterility, Certificates of Analysis, and Certificates 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 sales@sterile.com or visit our website at www.sterile.com.

Patents: www.sterile.com/patents