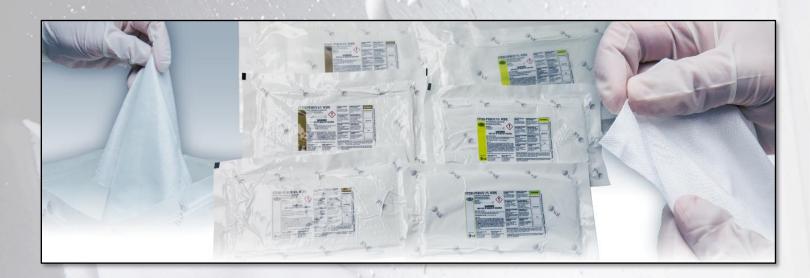


VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



STERI-PEROX® Wipe 3% & 6%

Hydrogen Peroxide and Water for Injection Solution Pre-Saturated 100% Polyester Wipe

Claims, product registrations, and regulatory requirements may vary based on local, regional, and/or national laws and regulations. Please contact your local sales representative for information specific to your region.

22FEB2024

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Product Overview

STERI-PEROX[®] **Wipes** are saturated with a ready-to-use 3% or 6% concentration of hydrogen peroxide solution formulated with USP 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) and 9"x9" (23 cm x 23 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 with lot specific analytical, conformance, and sterility data, tested to current USP compendium.

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 USP Water for Injection (<0.45 EU/mL)
- 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

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" or 9"x9" size
- Delivered with lot specific analytical, conformance, and sterility data, tested to current USP compendium



Ported Bag for Aseptic 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

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



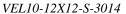
Chemical Specifications

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%, 12"x12", 20 wipes/bag, 10 bags/case, Non-Sterile	200	
VEL10-12X12-S-3016	STERI-PEROX Wipe 6%, 12"x12", 20 wipes/bag, 10 bags/case, Sterile	200	
VEL10-9X9-S-3034	STERI-PEROX Wipe 6%, 9"x9", 20 wipes/bag, 10 bags/case, Sterile	200	
VEL10-12X12-3015	STERI-PEROX Wipe 3%, 12"x12", 20 wipes/bag, 10 bags/case, Non-Sterile	200	
VEL10-12X12-S-3014	STERI-PEROX Wipe 3%, 12"x12", 20 wipes/bag, 10 bags/case, Sterile	200	
VEL10-9X9-S-3035	STERI-PEROX Wipe 3%, 9"x9", 20 wipes/bag, 10 bags/case, Sterile	200	







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



STERI-PEROX® 3% Wipe

Sterile Pharmaceutical Cleanroom Wipe

Hydrogen Peroxide at 3.00% v/v Saturated

Ingredients:

WARNING

KEEP OUT OF THE REACH OF CHILDREN



Veltek Associates, Inc. 15 Lee Blvd. Malvern, PA 19355-1234 USA Tel: 1-610-644-8335

www.sterile.com

Case No.: VEL10-PEROX-3%-00 ● Rev 6/20

Patents: www.sterile.com/patents

Made in Korea to VAI quality standards

DIRECTIONS FOR USE

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

FOR INDUSTRIAL USE ONLY. Not for personal 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. **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.

HAZAR 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.

For Spill/Exposure Emergency Response Service from the USA or Canada call CARECHEM 24 at 866-928-0789. From the EU all 44 1235 239 670 or Arabic call 011-44-1235-239-671.



STERI-PEROX® 6% Wipe

Sterile Pharmaceutical Cleanroom Wipe

Wipe saturated with 6% Hydrogen Peroxide

Ingredients:

Hydrogen Peroxide (CAS 7722-84-1)...............6.0%

Other Ingredients: Water



Manufactured By:

Veltek Associates, Inc. 15 Lee Blvd, Malvern, PA 19355-1234 USA Tel: 1-610-644-8335 • www.sterile.com

Case#: VEL10-PEROX-6% ● Rev 12/20 Patents: www.sterile.com/patents

Made in Korea to VAI quality standards

WARNING. Causes serious eye irritation.

PRECAUTIONS FOR USE:

Wash hand thoroughly after handling. Wear eye protection, protective gloves. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

See container for lot# / Exp Date

SDS: VEL-037-6 (Americas), VEL-037-6-EU (Europe)

EMERGENCY NUMBER: 1-866-928-0789 (toll free USA), 1-800-579-7421 (toll free Canada), 1-215-207-0061 (Americas), +44 1235 239670 (Europe), +44 1235 239671 (Middle East/Africa), +353 (0)1 809 2166 (Ireland, available to the public 08.00-22.00), 000 800 100 7479 (Hindi).

See Safety Data Sheet for first aid and additional product information.

For Industrial Use Only.



Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Safety Data Sheet
- Product Validation
- Sample lot specific documentation packages delivered with lot specific analytical, conformance, and sterility data, tested to current USP compendium



VAI®'s Wiper Family

VAI's Sterile Chemical Manufacturing Division (SCMD) manufactures a complete range of cleaning agents and disinfectants that are used daily in cleanroom operations. Overall, VAI's capabilities for manufacturing products include the ability to fill aerosol, bulk, and unit dose packages in ISO 5 or 7 (Grade A/B). Our aseptic filling operations are coupled with the validated and proven ability to irradiate a final product. Assurances are taken in every aspect of SCMD concerning sterility and particulate removal. VAI's operations mirror current GMP's and enforces the adherence to USP specifications. VAI is an EPA and FDA registered facility.

For more information call 610-644-8335, email <u>sales@sterile.com</u> or visit our website at www.sterile.com. Patents: www.sterile.com/patents