



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



HYPO-CHLOR[®] Wipe 0.25% & 0.52%, and 5.25%

Sodium Hypochlorite and Water for Injection Solution
Pre-Saturated 100% Polyester Wipe

Product Overview

HYPO-CHLOR® Wipes are saturated with a ready-to-use 0.25%, 0.52%, or 5.25% concentration of sodium hypochlorite 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 a sodium hypochlorite spray could create an excess of residue. Pre-saturated wipers, including **HYPO-CHLOR Wipes**, can prevent the overuse of chemicals and reduce costs. **HYPO-CHLOR Wipes** are available in a standard 12"x12" (30.5 cm x 30.5 cm) size and either sterile or non-sterile.

HYPO-CHLOR 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. **HYPO-CHLOR Wipes** are delivered each time with lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Conformance.

The material used in our **HYPO-CHLOR 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 **HYPO-CHLOR Wipes** are packaged in an opaque, zip-lock style, ported bag that 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 or other critical environments. In addition, **HYPO-CHLOR Wipe 0.52%** is available individually packaged in an opaque, easy-tear style bag.

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
- Where a sodium hypochlorite spray would create excess residue
- To prevent overuse of sodium hypochlorite when compared to using trigger sprayers or gallon pour

Quality and Manufacturing

- Wipe material laundered in ISO 4 (Grade A/B, Former Class 10)
- Sodium hypochlorite solution is filtered at 0.2 microns
- Formulated with Water for Injection
- Filled in ISO 5 (Grade A/B, Former Class 100)
- 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 into sterile components

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, zip-lock style, easy tear bag
- Re-sealable for continued use after opening
- Individually labeled with lot number and expiration
- Three concentrations: 0.25%, 0.52%, or 5.25% to fit your specific needs
- For use on multiple surfaces and 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" (30.5 cm x 30.5 cm) size
- Delivered with lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Conformance



Easy Tear Packaging



Zip-Lock Style Bag

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

HYPO-CHLOR Wipe – Laundered Polyester Wipe	
Material Details	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 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

HYPO-CHLOR Wipe – Sodium Hypochlorite and Water for Injection	
Certificate of Analysis	Specifications
Assay 0.25%:	0.25% - 0.30% w/w
Assay 0.52%:	0.4% – 0.6% w/w
Assay 5.25%	4.0% - 6.0% w/w
Litmus Paper Turns Blue:	Pass
Addition of HCL Gives Off CL2 Gas:	Pass
Yellow Flame Test:	Pass
Expiration Period:	18 months

Ordering Information

HYPO-CHLOR Wipe – Sodium Hypochlorite and Water for Injection		
Part number	Description	Qty/Case
VEL9-12X12-S-3020	HYPO-CHLOR® Wipe 0.25%, 20 wipes/bag, 10 bags/case, Sterile	200
VEL9-12X12-3021	HYPO-CHLOR Wipe 0.25%, 20 wipes/bag, 10 bags/case, Non-Sterile	200
VEL9-12X12-S-3018	HYPO-CHLOR Wipe 0.52%, 20 wipes/bag, 10 bags/case, Sterile	200
VEL9-12X12-3019	HYPO-CHLOR Wipe 0.52%, 20 wipes/bag, 10 bags/case, Non-Sterile	200
VEL9-12X12-S-3026	HYPO-CHLOR Wipe 0.52%, Individually Packaged, Sterile	100
VEL9-12X12-S-3025	HYPO-CHLOR Wipe 5.25%, 20 wipes/bag, 5 bags/case, Sterile	100



VEL9-12X12-3021



VEL9-12X12-S-3026



VEL9-12X12-S-3025

PRODUCT LABELING

HYPO-CHLOR® Wipe 0.25%, 0.52%, & 5.25%
Sodium Hypochlorite and Water for Injection Solution

(Any specific product label is available upon request.)



HYPO-CHLOR Wipe Family

HYPO-CHLOR® Wipe 0.25%, 0.52%, & 5.25%

Sterile Pharmaceutical Cleanroom Wipe Class 10 Laundered Sealed Edge Polyester Wipe

HYPO-CHLOR Wipe 0.25%
Sodium Hypochlorite at 0.25% wt./wt.
in USP Water for Injection

Ingredients 0.25%:
Sodium Hypochlorite0.25%
USP Water for Injection.....99.75%
Total100%
SDS# VEL-131

HYPO-CHLOR Wipe 0.52%
Sodium Hypochlorite at 0.52% wt./wt.
in USP Water for Injection

Ingredients 0.52%:
Sodium Hypochlorite0.52%
USP Water for Injection.....99.48%
Total100%
SDS# VEL-131

HYPO-CHLOR Wipe 5.25%
Sodium Hypochlorite at 5.25% wt./wt.
in USP Water for Injection

Ingredients 5.25%:
Sodium Hypochlorite5.25%
USP Water for Injection.....94.75%
Total100%
SDS# VEL-119

KEEP OUT OF THE REACH OF CHILDREN WARNING



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.

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

Made in USA. **Manufactured by:**

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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

If in Eyes: Remove contact lenses; rinse with plenty of water. **If Swallowed:** Drink milk or water; get prompt medical attention; avoid alcohol. **If contact with Skin:** Remove clothing and wash skin.

WARNING. HAZARD STATEMENTS:

Causes skin irritation. Causes serious eye irritation. Very toxic to aquatic life.

PRECAUTIONARY STATEMENTS

Do not breathe mist. Wash thoroughly after handling. Wear chemical resistant gloves/protective clothing/eye protection/face protection. Avoid release into the environment.

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
 - **HYPO-CHLOR Wipe 0.25%** - SDS# VEL-131
 - **HYPO-CHLOR Wipe 0.52%** - SDS# VEL-130
 - **HYPO-CHLOR Wipe 5.25%** - SDS# VEL-119
- 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