

# HYPO-CHLOR<sup>®</sup> Wipe

5.25%, 0.52% & 0.25%

Sodium Hypochlorite Solution Saturated Wipe

hcw-01-EU Rev 15 November 2012

## Technical Data File



# HYPO-CHLOR<sup>®</sup> Wipe

A Superior Methodology for Performing Compliant and Effective  
Sodium Hypochlorite Applications

- ✓ Available in 0.25%, 0.52%, 5.25% and custom formulations
- ✓ Formulated with Water for Injection Quality Water
- ✓ Ready-to-use
- ✓ Available in the ABCD Clean Room Introduction System
- ✓ Ideal for product spills
- ✓ Class 10 Cleanliness
- ✓ Ultra absorbent wipe material
- ✓ Class 10 Laundered
- ✓ Completely tested according to current USP compendium
- ✓ Lot specific Certificate of Analysis and Sterility
- ✓ Completely traceable
- ✓ Completely validated for sterility and shelf life
- ✓ Dried in ULPA filtered class 1 air stream
- ✓ Laundered with Di Water
- ✓ FocusEdge Cutting Technology
- ✓ 12" x 12" size
- ✓ 20 wipes/pack folded for easy removal
- ✓ Re-sealable packaging



*Quality Choice from the Innovators in Clean Room Technology!*

### Utilizing a Sterile Sodium Hypochlorite Wipe in Operations

In most facilities sodium hypochlorite is routinely used in decontamination operations. At times, the spray of the sodium hypochlorite may be considered inappropriate due to possible over spray or in relation to the delicacy of instrumentation or process lines.

The use of sodium hypochlorite is an effective means without the problematic user problems relating to vapors associated with the use of a peracetic acid and hydrogen peroxide.

To meet end user requirements and in light of the possible constraints in the application of the spray of sodium hypochlorite, Veltek Associates, Inc. has developed HYPO-CHLOR® Wipe.

In development of the “sterile” version of the HYPO-CHLOR® Wipe the problematic issue surrounded the inability to irradiate a sodium hypochlorite solution due to instability issues. Sodium hypochlorite solutions degrade chlorine during the irradiation process. This leaves the solution as sodium chloride and water. This problematic situation provides the inability to gamma irradiate a final bleach solution and so it was VAI’s task to develop a system whereby a tested sterile saturated wipe could be made available to the industry.

Developing a successful manufacturing scenario, VAI’s HYPO-CHLOR® Wipe is available in a 0.25% and 0.52% sodium hypochlorite wipe made with USP Water for Injection. The product is aseptically filled with the utilization of pre-irradiated components through VAI’s patented *Asepti-Fill* system. This system provides the ability to fill a 0.2 micron filtered sodium hypochlorite solution through a closed system into pre-irradiated bags of wipers within a Class 100 (Grade A, ISO 5) manufacturing area. The closed system bag is filled, labeled and double bagged and placed into a double lined case.

The use of HYPO-CHLOR Wipes is normally for intricate, or sensitive locations where a spray down that would create an overage of residue is not desired. HYPO-CHLOR Wipe answers these difficult decontamination situations.

### Why Choose HYPO-CHLOR® Sterile Wipe for Aseptic Manufacturing Operations?



- ✓ Eliminates the use of a non-sterile, non-filtered sodium hypochlorite wipe in operations
- ✓ Enables the reduction of spraying of sodium hypochlorite on sensitive machinery
- ✓ Ideal for product spills
- ✓ Class 10 Cleanliness
- ✓ Ultra Absorbent Wipe Material
- ✓ FocusEdge Cutting Technology
- ✓ Class 10 Laundered
- ✓ Available in 0.25%, 0.52% and Custom Formulations
- ✓ Validated Sterile to  $10^{-6}$  SAL
- ✓ Extremely low particulate shedding & soluble extracts



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# HYPO-CHLOR<sup>®</sup> Wipe

## The Superior Methodology for Performing Compliant Sodium Hypochlorite Wipe Applications Sterile and Non-Sterile

### Product Description:

HYPO-CHLOR<sup>®</sup> Wipe 0.25% or 0.52% is a superior saturated sodium hypochlorite wipe used for both aseptic and non-aseptic wipe downs of filling and packaging machinery, stainless steel surfaces, lexan, polycarbonate, glass and any critical surface requiring to be cleaned. The wipe is a laundered polyester dry wipe that incorporates Class 10 cleanliness and extremely low particulate shedding and soluble extracts. The wipe is available in a 12" X 12" size both sterile and non-sterile. The wipe is then saturated with a ready to use 0.25% or 0.52% sodium hypochlorite solution in WFI. The sterile version is assembled with terminally sterilized components and each order is delivered with the lot specific Certificate of Analysis and Certificate of Sterility (current USP compendium). The material used in the product is a 100% continuous polyester fiber that is especially clean and absorbent. Particulate, residues and foreign matter are 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. The edges are cut using FocusEdge technology. HYPO-CHLOR<sup>®</sup> clean room wipes are extremely low in particle shedding and soluble extractables. They are laundered in ultra-filtered water of 0.45 $\mu$  and dried in a HEPA filtered Class 1 air stream. Each wipe is inspected and hermetically sealed in ultra clean packages within class 10 conditions. HYPO-CHLOR<sup>®</sup> Wipe clean room wipes are your choice to meet the highest cleanroom standards.

### Ordering Information:

Order#	Description	Quan/Case
VEL9-12X12-3021	HYPO-CHLOR <sup>®</sup> 0.25% Wipe Non-Sterile - 20 wipes/bag, 10 bags/case	200
VEL9-12X12-S-3020	HYPO-CHLOR <sup>®</sup> 0.25% Wipe Sterile - 20 wipes/bag, 10 bags/case	200
VEL9-12X12-3019	HYPO-CHLOR <sup>®</sup> 0.52% Wipe Non-Sterile - 20 wipes/bag, 10 bags/case	200
VEL9-12X12-S-3018	HYPO-CHLOR <sup>®</sup> 0.52% Wipe Sterile - 20 wipes/bag, 10 bags/case	200



**Quality  
Manufacturing**



**Superior Cleanliness  
Excellent Absorbency  
Particulate/Residue Entrapment**



**Tested for Particulates  
Extractables & Sterility**

# HYPO-CHLOR<sup>®</sup> Wipe

## The Superior Methodology for Performing Compliant Sodium Hypochlorite Wipe Applications Sterile

### Product Description:

VAI's saturated 5.25% sodium hypochlorite wipes are formulated to address the sterile pharmacy compounding departments needs. Worker safety is compromised if cytotoxic drug residues are left behind on the work area surfaces and employee exposure to those drugs are possible.

HYPO-CHLOR 5.25% wipes are sterile and non-shedding which is ideally suited for introduction into the ISO 5 areas. Saturated wipes eliminate the need for additional handling and mixing of different materials for application. The saturated wipes also maximize excess solution and possible aerosolization of the active ingredient (NaOCl<sub>2</sub>) for optimal worker safety.

### Application:

Appropriate PPE's (personal protective equipment) should be donned when using this or any other chemical agent. This includes appropriate gloves and eye wear protection.

Open the sterile saturated wipe pack by finding the easy-tear "notch". Remove the saturated wipe and apply liberally to the area to be treated and allow to stand for 15 seconds.

Remove the applied wiper solution and do not allow the solution to dry on the surface for an extended period of time. Cleaning (removal) prevents permanent etching of the stainless or ceramic substrates caused by the NaCl<sub>2</sub> solution and may be performed by using sterile 70% IPA, WFI water or DEC-Clean<sup>®</sup>. All cleaning agents should be applied and removed with a sterile non-shedding dry wipe such as WipeDOWN<sup>®</sup>.

Dispose of the used wipes in an approved chemotherapy waste container.

### Ordering Information:

Order#	Description	Quan/Case
VEL9-12X12-3025	HYPO-CHLOR <sup>®</sup> 5.25% Wipe Sterile - 20 wipes/bag, 5 bags/case	100

## HYPO-CHLOR<sup>®</sup> Wipe

### SPECIFICATIONS

Fibers:	100% knitted and laundered polyester	
Construction:	Continuous Monofilament	
Basis Weight:	130 ± 5gsm	
Thickness:	0.56 – 0.64 mm	
Sorbency:	450 Capacity (mL/sq M)	
Drop Sorbency:	0.2	
Color:	White	
Classification Compatibility:	Class 10	
<b>Liquid Particles</b>	<b>≥ 0.5µm</b>	<b>≥ 5.0µm</b>
Biaxial Shake Test	8.0 x 10 <sup>6</sup>	0.50 x 10 <sup>6</sup>
Planner Shake Test	4.2 x 10 <sup>6</sup>	0.25 x 10 <sup>6</sup>
Ready Releasable	2.0 x 10 <sup>6</sup>	0.15 x 10 <sup>6</sup>
<b>Airborne Particles</b>	<b>0.5µm</b>	<b>5.0µm</b>
Helmke Drum	4000	1500
<b>Specific Ion Content:</b>	<b>PPB</b>	
Sodium	< 100	
Lithium	< 100	
Calcium	< 100	
Potassium	< 100	
Manganesse	< 100	
Aluminum	< 100	
Chloride	< 100	
Floride	< 100	
Phosphate	< 100	
Sulfate	< 100	
Nitrate	< 100	

### GENERAL PRODUCT PACKAGING/FILLING SPECIFICATIONS:

- PRODUCT LOT NUMBER:** Product Lot Number is placed on each wiper package and on the exterior of the case.
- IRRADIATION LOT NUMBER:** Irradiation Sterilization Lot Number for components appear in the batch formula documentation for the applicable components that are pre-sterilized.
- PACKAGING:** Product is packaged twenty (20) folded wipes in a re-sealable bag. The re-sealable bag is double-bagged in a 4 mil poly bag. These packs are placed into a double lined case.
- STERILITY TESTING:** Once processing has been accomplished, the product undergoes 14 day USP <71> Direct Transfer Method in TSB (Trypticase Soy Agar) and Thioglycollate Media. (20 samples/lot)
- EXPIRATION:** Expiration is 2 years from date of manufacture.
- DOCUMENTATION:** Delivered with the Lot Specific Certificate of Analysis and Certificate of Sterility.