VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES

WIPEDOWN™ 1-2-3
3 Step Applicator Kit

Sterile Wipe Kit

For addressing USP <800> Hazardous Drugs - Handling in Healthcare Settings

Product Overview

VAI's **WipeDown® 1-2-3** has been designed to address the risk of occupational exposure to most hazardous drugs during compounding sterile preparations, and administering, as outlined in USP <800>. **WipeDown 1-2-3** is a sterile 3-step application kit including individually packaged saturated wipes with 5.25% sodium hypochlorite, 2% sodium thiosulfate with surfactant, and 70% isopropyl alcohol. When used in sequence, the three sterile saturated wipers provide deactivation, decontamination, and cleaning of sterile compounding surfaces from most hazardous drugs.

Each WipeDown 1-2-3 *Sterile* Kit Contains:

- Step #1 – HYPO-CHLOR® Wipe, USP 5.25% sodium hypochlorite for deactivation
- Step #2 – THIO-WIPE®, 2% USP sodium thiosulfate with surfactant for decontamination
- Step #3 – ALCOH-WIPE®, 70% USP isopropyl alcohol for cleaning

WipeDown 1-2-3 wipes consist of non-shedding, 12"x12" premium 100% polyester wiper materials that are designed to be exceptionally clean, to have excellent absorption capabilities, and to provide a substantial 9 square foot surface coverage. Both polyester fabrics are soft, strong, and have outstanding non-shedding particulate performance. Each material has been chosen for its specific compatibility with each chemical.

All three chemical components used in **WipeDown 1-2-3** are formulated with Water for Injection (WFI) and filtered at 0.2 microns. Each wiper is individually packaged with sterility assured through gamma irradiation and/or aseptic filtration into gamma irradiated sterile components. Each delivery of **WipeDown 1-2-3** comes with a lot specific certificate that includes analysis, sterility, and irradiation information. Each kit containing three individually packaged wipers is bagged and packaged into a liner bag for easy transport into the sterile area. Each kit is labeled with lot number and expiration date.

Sterile **WipeDown 1-2-3** Kit

Product Use

USP <797> Pharmaceutical Compounding - Sterile Preparations require that the materials that enter the ISO 5 classified area to be sterile to satisfy good aseptic practices. Whereas, USP <800> Hazardous Drugs – Handling in Healthcare Settings requires hazardous drug deactivation in compounding sterile preparations for patient and handler protection. **WipeDown 1-2-3** assures the highest quality compounding sterile preparations program possible by developing a *sterile* three step kit to deactivate most hazardous drugs.

Product Packaging

Each "kit" contains three sterile saturated wipers that are individually packaged in opaque, easy-tear style bags. Each kit is additionally, individually singled bagged in an easy-tear style bag. Each box of **WipeDown 1-2-3** contains 10 kits wrapped in a secondary box liner bag. There are 12 boxes per master case. **WipeDown 1-2-3** is sold per master case but is also available by individual "boxes" through many of our numerous healthcare distributors.

WipeDown 1-2-3 Product Packaging: 3 wipes/kit, 10 kits/box

Ordering Information

WipeDown 1-2-3 Sterile Wipe Kit			
Part number	**Description**	**Qty/box**	**Qty/cs**
VEL13-12X12-S-123	WipeDown 1-2-3, 3 Step Applicator Kit, 3 wipes/kit, Sterile	10 kits, 30 wipes	12 boxes, 120 kits, 300 wipes

Bulk Packaging

In addition to the **WipeDown 1-2-3** kit, VAI offers bulk packaging of all three **WipeDown 1-2-3** wipe components for the convenience of more frequent applications. VAI's HYPO-CHLOR® 5.25% Wipe, a saturated 12"x12" sodium hypochlorite to a 5.25% concentration wipe, corresponds to Wipe #1 in the **WipeDown 1-2-3** kit. Secondly, VAI's THIO-WIPE® 2%, a

saturated 12”x12” sodium thiosulfate to a 2% concentration with added surfactant wipe, corresponds to Wipe #2 in the **WipeDown 1-2-3** kit. Finally, VAI’s Process2Wipe® IPA 70, a saturated 9”x9” 70% isopropyl alcohol and 30% Water for Injection wipe, corresponds to Wipe #3 in the **WipeDown 1-2-3** kit.

Ordering Information

Bulk Packaging Ordering Information			
Part number	**Description**	**Qty/box**	**Qty/cs**
VEL9-12X12-S-3025	HYPO-CHLOR® 5.25% Wipe, 12”x12”, Sodium Hypochlorite 5.25%, Zip-Lock Style Packaging, Sterile	20 wipes/bag	5 bags/case, 100 wipes
VEL13-12X12-S-3033	THIO-WIPE® 2% Wipe, 12”x12”, Sodium Thiosulfate 2% with Surfactant, Peel & Reseal Style Packaging, Sterile	20 wipes/bag	10 bags/case, 200 wipes
VEL12-9X9-S-3032	Process2Wipe IPA 70 Wipe, 9”x9”, Isopropyl Alcohol 70%, Peel & Reseal Style Packaging, Sterile	50 wipes/bag	20 bags/case, 1000 wipes

VEL9-12X12-S-3025

VEL13-12X12-S-3033

VEL12-9X9-S-3032

Step #1: HYPO-CHLOR® Wipe 5.25%

Wiper #1 of **WipeDown 1-2-3** is saturated with a sterile 5.25% sodium hypochlorite solution formulated with Water for Injection (WFI) for deactivation of most hazardous drugs. This HYPO-CHLOR Wipe 5.25% protects the compounding preparers by deactivating the potentially active drugs present on the compounding surface. When used as directed, HYPO-CHLOR Wipe 5.25% and subsequent wipes ensure the surface is rendered clean and decontaminated for future handlers.

Therefore, it ensures that these compounding preparations are following USP <797> protocol along with USP <800> compliance for hazardous drugs - handling in healthcare settings.
Wiper #1, HYPO-CHLOR Wipe 5.25% is a 12”x12” premium, knitted, 100% polyester wipe that has low shedding characteristics. Each wipe treats approximately a 9 square foot area for optimal surface deactivation of most hazardous drugs present within the compounding operation. Each HYPO-CHLOR Wipe 5.25% comes individually packaged. The HYPO-CHLOR Wipe 5.25% is manufactured via aseptic fill at 0.2 microns into gamma irradiated sterile components in ISO 5 (Grade A/B, Former Class 100). Lot specific certificate with analysis, sterility, and irradiation information is issued and delivered with each shipment.

Quality and Manufacturing

- Aseptically filled components sterilized via gamma irradiation
- Assayed according to current USP compendium
- Filtered at 0.2 microns
- Sodium hypochlorite solution is formulated with Water for Injection
- Lot sterility tested according to current USP compendium
- Completely lot traceable

Features and Benefits

- Delivered with lot specific documentation
- 12” x 12” in size
- Wipe folded for easy removal
- Each kit is individually labeled with lot number and expiration date
- Packaged in an opaque, easy-tear style bag
- Wiper is individually packaged
- Kit is single bagged sterile with one box liner bag
- 100% synthetic filament polyester constructed in a continuous knit that minimizes fiber and particulate release
- Designed to comply with USP <797>
- Deactivates most hazardous drugs present on compounding surface
- Ready-to-use

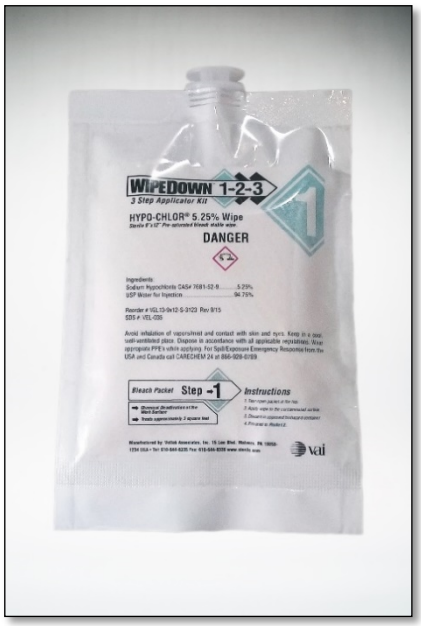
Chemical Specifications

WipeDown 1-2-3 Step #1 – HYPO-CHLOR® Wipe 5.25%	
Certificate of Analysis	**Specification**
Assay Test:	4.0 - 6.0% w/w
Litmus paper turns blue:	Pass
Addition of HCL gives off CL2 gas:	Pass
Yellow Flame Test:	Pass
Sterility:	Aseptic Fill
Shelf Life:	1 year

Material Specifications

WipeDown 1-2-3 Step #1 – HYPO-CHLOR Wipe 5.25%*	
Material Details	**Specification**
Material:	100% Polyester
Color:	White
Construction:	Continuous filament knitted construction
Thickness:	0.56 – 0.64 mm
Sorption Capacity:	>=270 mL/m^2

*Treats approximately 9 square feet



Step 1: HYPO-CHLOR 5.25%

WipeDown 1-2-3 Steps 1 - 3

Step #2: THIO-WIPE® 2%

Wiper #2 of **WipeDown 1-2-3** is saturated with 2% USP sodium thiosulfate solution formulated with Water for Injection (WFI) and surfactant. The sodium thiosulfate solution has been specifically developed for cleaning, decontaminating, and neutralizing the sodium hypochlorite solution and previously deactivated hazardous drugs. Sodium thiosulfate protects the stainless steel compounding surface from corrosion and pitting due to the presence of harsh sodium hypochlorite and potent, hazardous drugs. Cleaning the surface from these residues improves the overall longevity of the sterile compounding equipment while staying USP <797> and USP <800> compliant.

Wiper #2, THIO-WIPE 2% wipe is a 12”x12” premium, non-woven, 100% polyester wipe that has low shedding characteristics. Each wipe treats approximately a 9 square foot area for optimal surface decontamination present within the compounding operation. Each THIO-WIPE 2% wipe comes individually packaged. THIO-WIPE 2% is filled in ISO 5 (Grade A/B, Former Class 100), filtered at 0.2 microns, and subsequently gamma irradiated. Lot specific certificate with analysis, sterility, and irradiation information is issued and delivered with each shipment.

Quality and Manufacturing

- Gamma irradiated
- Assayed according to current USP compendium
- Filtered at 0.2 microns
- Sodium thiosulfate solution is formulated with Water for Injection
- Lot sterility tested according to current USP compendium
- Completely lot traceable

Features and Benefits

- Delivered with lot specific documentation
- 12” x 12” in size
- Wipe folded for easy removal
- Each kit is individually labeled with lot number and expiration date
- Packaged in an opaque, easy-tear style bag
- Wiper is individually packaged
- Kit is single bagged sterile with one liner bag
- Material is low in particulate shedding and soluble extractables
- Designed to comply with USP <797>
- Decontaminates post deactivation of hazardous drug
- Protects stainless steel compounding surfaces from corrosion and pitting
- Ready-to-use

Chemical Specifications

WipeDown 1-2-3 Step #2 – THIO-WIPE® 2%	
Certificate of Analysis	**Specification**
Appearance:	Clear, free of suspended matter
Solubility in Water:	Completely
pH:	6.0 - 9.5
Assay:	1.8%-2.2%
Sterility:	Gamma irradiation
Shelf Life:	1 year

Material Specifications

WipeDown 1-2-3 step #2 – THIO-WIPE 2%*		
Material Details	**Specification**	**Test Method**
Material:	100 % Polyester	N/A
Composition:	Non-woven	N/A
Color:	White	N/A
Basis Weight:	2.0 oz/yd^2	ASTM D3776
Thickness:	0.51 mm	ASTM D5034

*Treats approximately 9 square feet

Step 2: THIO-WIPE 2%

WipeDown 1-2-3 Steps 1 - 3

Step #3: ALCOH-WIPE® 70% IPA

Wiper #3 of **WipeDown 1-2-3** is 70% USP isopropyl alcohol formulated with 30% Water for Injection (WFI). The ALCOH-WIPE 70% IPA provides an additional measure against contaminates present on the compounding surfaces for added patient and preparer's protection. After deactivation of the work surface, additional cleaning is needed in order to maintain a critical and controlled work environment for compounding sterile products. Once the surface has been fully treated by all three wipes in the **WipeDown 1-2-3** kit, the surface will be able to return to its natural composition.

Wiper #3, ALCOH-WIPE 70% IPA wipe is a 12"x12" premium, non-woven, 100% polyester wipe that has low shedding characteristics. Each wipe treats approximately a 9 square foot area for optimal isopropyl alcohol wipe down on surfaces present within the compounding operation. Each ALCOH-WIPE 70% IPA wipe comes individually packaged. ALCOH-WIPE IPA 70% is filled in ISO 5 (Grade A/B, Former Class 100), filtered at 0.2 microns, and subsequently gamma irradiated. Lot specific certificate with analysis, sterility, and irradiation information is issued and delivered with each shipment.

Quality and Manufacturing

- Gamma irradiated
- Assayed according to current USP compendium
- Filtered at 0.2 microns
- Isopropyl alcohol is formulated with Water for Injection
- Lot sterility tested according to current USP compendium
- Completely lot traceable

Features and Benefits

- Delivered with lot specific documentation
- 12" x 12" in size
- Wipe folded for easy removal
- Each kit is individually labeled with lot number and expiration date
- Packaged in an opaque, easy-tear style bag
- Wiper is individually packaged
- Kit is single bagged sterile with one box liner bag
- Material is low in particulate shedding and soluble extractable
- Designed to comply with USP <797>
- Provides added protection from contaminates on the work surface
- Ready-to-use

Chemical Specifications

WipeDown Step #3 – ALCOH-WIPE® 70% IPA	
Certificate of Analysis	**Specification**
Appearance:	Clear Colorless
Assay Test:	68.0-72.0%
Acidity Test:	≤ 1.0 ml
Nonvolatile Residue Test:	< 5.0 mg
Specific gravity @ 20 degrees C:	0.872-0.883
Sterility:	Gamma irradiation
Expiration Dating:	1 year

Material Specifications

WipeDown Step #3 – ALCOH-WIPE 70% IPA*		
Material Details	**Specification**	**Test Method**
Material:	100 % Polyester	N/A
Composition:	Non-woven	N/A
Color:	White	N/A
Basis Weight:	2.0 oz/yd^2	ASTM D3776
Thickness:	0.51 mm	ASTM D5034

*Treats approximately 9 square feet

Step 3: ALCOH-WIPE 70% IPA

WipeDown 1-2-3 Steps 1 - 3

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Additional Documentation

The following documentation is available upon request:

- Specific Product Testing Reports
- Safety Data Sheet
    - **WipeDown 1-2-3** Step #1 – SDS# VEL-119
    - **WipeDown 1-2-3** Step #2 – SDS# VEL-146
    - **WipeDown 1-2-3** Step #3 – SDS# VEL-121-AW
- Sample lot specific certificate with Analysis, Irradiation, and Sterility information

Veltek Associates, Inc. covers every aspect of cleaning and decontaminating necessary for full compliance to USP including consultation from industry experts on setting up and maintaining aseptic processes during the compounding of sterile products. VAI has a complete line of sterile cleaning agents and disinfectants with easy to use sterilizable cleaning systems. The Core2Clean® Plus System addresses the cleaning and disinfection of environmental surface areas. The SimpleMix® System provides easy-to-use disinfectants in a pre-measured container system. In addition, VAI offers complete line of sterile, individually packaged, saturated wipes.

To further address the requirements, VAI provides a unique innovative gowning system to address aseptic gowning requirements. Furthermore, the easy to use SMA air samplers are an accepted industry standard that simplifies microbial air testing in aseptic compounding areas. As the compounding pharmacy industry moves forward to require greater control of environmental production areas, be assured VAI is one step ahead with innovation and support.

Please visit our website www.sterile.com or call 1-888-4-STERILE for more information regarding our products and services for USP <797> compliance. Patents: www.sterile.com/patents