



VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES



DECON-HAND®

FDA Registered Ethanol Based Hand Sanitizer

Product Description

Veltek Associates, Inc. manufactures an ethanol based, gelled, instant hand sanitizer, **DECON-HAND**, that has been processed to comply with the standards required by the pharmaceutical, biotechnology, medical device, and healthcare industries. **DECON-HAND** complies with the requirements for transport into classified areas within the cleanroom operation, therefore, making it an ideal product for hand sanitizing before glove donning in gowning rooms. Sanitizing before glove donning is recommended to reduce cross contamination within the cleanroom environment. **DECON-HAND** is manufactured in accordance with 21 CFR Part 211 Good Manufacturing Practices for Drugs and the Tentative Final Monograph for Topical Antimicrobial Drug Products for Over-The-Counter use. This is a USA FDA registered product NDC# 64307-001.

DECON-HAND is available in a two sizes, the 16oz bottle and the 32oz ASEPTI-CLEANSE, hands free dispensing system, bottle in either sterile or non-sterile versions. The 16oz bottle is delivered with an attachable hand pump or can be mounted directly to the wall for convenient sanitizing. **DECON-HAND** is filled in an ISO 5 (Grade A/B, former Class 100) operation, filtered, and subsequently gamma irradiated at 10^{-6} SAL. All lots of **DECON-HAND** are sterility tested according to the current USP compendium and are completely lot traceable from start to finish. Each shipment of **DECON-HAND** is delivered with lot documentation materials including a Certificate of Sterility, Certificate of Irradiation, and a Certificate of Analysis. **DECON-HAND** is packaged quadruple bagged using the ABCD Cleanroom Introduction System™, and has been completely validated for sterility and shelf life.

Quality and Manufacturing

- Gamma irradiated at a 10^{-6} SAL
- Filled in an ISO 5 (Grade A/B, Former Class 100) operation
- Each container is double bagged packaged sterile and available in our ABCD Cleanroom Introduction System™
- Completely lot traceable and has been validated for sterility and shelf life
- Filtered
- Delivered each time with lot specific documentation and safety material
- Sterility tested according to current USP Compendium
- Manufactured in accordance with 21 CFR Part 211 Good Manufacturing Practices for Drugs

DECON-HAND – FDA Registered Ethanol Based Hand Sanitizer	
Certificate of Analysis	Result
Color:	Water Like
Clarity:	Clear
Odor:	Mild Ethanol
Density @ 25 c:	7.13-7.54 lb./ga.
Ethanol:	58.7-71.0%
pH:	6.0-8.0
Viscosity:	5,000 to 30,000cps
Expiration Period:	3 years

Uses

DECON-HAND is used as an instant hand sanitizer before glove donning. It can be used throughout the entire facility.

Features and Benefits

- Available in the ABCD Cleanroom Introduction System™
- Container size available for our hands free dispensing system, ASEPTI-CLEANSE
- Can be mounted directly to gowning room walls using the DH-100
- 16oz bottles delivered with an optional attachable pump
- Convenient hand sanitizing before glove donning
- Ready-to-use
- FDA registered
- Available in sterile or non-sterile versions

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.

ASEPTI-CLEANSE Dispenser

The ASEPTI-CLEANSE is a hands-free dispensing system that allows for dosed quantities of **DECON-HAND** to be delivered without user contact. This dispensing system is the most advanced infrared sensor dispensing system available in the pharmaceutical and biotechnology industries. The ASEPTI-CLEANSE can be mounted directly to glass or walls, which makes it an excellent choice for gowning rooms and aseptic manufacturing areas. It can be set to dispense approximately 1, 2, or 3 mL of solution. Simply place your hand underneath to deliver a pre-measured dose of solution, to the hand, with no contact between the user and the ASEPTI-CLEANSE. The ASEPTI-CLEANSE is an excellent solution to hand or glove disinfection before or after glove donning.



DH-100

The DH-100 is an additional dispensing option for **DECON-HAND** 16 oz pump containers. VAI developed the DH-100 Dispenser to meet the requirements of cGMP cleanroom operations by reducing cross contamination and preventing overuse. The DH-100 can be mounted directly to the gowning room wall, is made of 316L stainless steel, and is fully autoclavable. It is excellent for hand sanitizing before glove donning.

216-P Dispenser

The 216-P pump dispenser is an additional pump made specifically for 16 oz containers of **DECON-HAND**. This pump dispenser simplifies the dispensing of **DECON-HAND** while delivering dosed quantities to prevent overuse. The 216-P comes individually double bagged and is irradiated sterile.

Ordering Information

DECON-HAND – FDA Registered Ethanol Based Hand Sanitizer		
Part number	Description	Qty/cs
DH-04	DECON-HAND, 16 oz, Attachable Pump, RTU, Non-Sterile	12
DH-06	DECON-HAND, 16 oz, Attachable Pump, RTU, Sterile	12
DH-09	DECON-HAND, 32 oz, ASEPTI-CLEANSE Bottle, Non-Sterile	12
DH-10	DECON-HAND, 32 oz, ASEPTI-CLEANSE Bottle, Sterile	12
216-P	216-P Dispenser, 16 oz Pump Dispenser, Individually Double Bagged, Sterile	12
DH-100	DH-100 Dispenser, 16 oz Bottle Compatible Wall Dispenser, 316 L Stainless Steel	1
DEC-301	ASEPTI-CLEANSE Hands Free Dispenser, for 32 oz Bottles	1




Veltek Associates, Inc.

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VAI's Product Label Colors


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 TOLL FREE: 888.478.3745 T: 610.644.8335 WWW.STERILE.COM
 VELTEK ASSOCIATES, INC.

VELTEK PRODUCT LABEL COLORS

PRODUCT NAME	BOTTLE/CAN COLOR	LABEL BACKGROUND COLOR	BAR & USER INFO COLOR	TEXT COLOR
DECON-AHOL WFI 70% AEROSOL	COOL GREY	PRINTED CAN COOL GREY		
DECON-AHOL WFI 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	COOL GREY		
DECON-AHOL WFI 70% SQUEEZE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI 70% ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI 60%	WHITE	WHITE		
DECON-AHOL WFI 91%	WHITE	WHITE		
DECON-AHOL WFI 99%	WHITE	WHITE		
STER-AHOL WFI AEROSOL	WHITE	PRINTED CAN WHITE		
STER-AHOL WFI TRIGGER SPRAY, 1 & 5 GALLON	WHITE	WHITE		
DECON-HAND STERILE	WHITE SEMI-TRANSPARENT	PRINTED BOTTLE		
DECON-HAND NON-STERILE	CLEAR	PRINTED BOTTLE		
DECON-HAND ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	WHITE		
STERI-OIL	WHITE	WHITE		
STERI-BUFFER	CLEAR	WHITE		
DECON-PHENE	WHITE	WHITE		
DECON-CYCLE	WHITE	WHITE		
DECON-CLEAN	WHITE	WHITE		
DECON-QUAT 100	WHITE	WHITE		
DECON-QUAT 200C	WHITE	WHITE		
DECON-QUAT 200V	WHITE	WHITE		
HYPO-CHLOR 0.25%	WHITE	WHITE		
HYPO-CHLOR 0.52%	WHITE	WHITE		
HYPO-CHLOR 5.25%	WHITE	WHITE		
STERI-PEROX 3%	WHITE	WHITE		
STERI-PEROX 6%	WHITE	WHITE		
DECON-SPORE 200 PLUS (SPORICIDE)	WHITE SEMI-TRANSPARENT	WHITE		
DECON-SPORE 200 PLUS (DISINFECTANT)	WHITE SEMI-TRANSPARENT	WHITE		
STEEL-BRIGHT	WHITE	WHITE		
STERI-SILICON	WHITE	BLACK		
DECON-GLASS	WHITE	WHITE		
VAI WFI QUALITY WATER	WHITE	WHITE		
STERI-WATER	WHITE	WHITE		

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PRODUCT LABELING

Any specific product label is available upon request.

Instant Hand Sanitizer

Manufactured By:

Veltek Associates, Inc.

15 Lee Blvd. Malvern, PA 19355-1234

Tel: 610-644-8335 • Fax: 610-644-8336

www.sterile.com

MSDS#: DH-98-01

NDC# 64307-001

Drug Facts

Active Ingredient:

Ethanol 64.5% (w/w).....antiseptic hand wash

Purpose:

Uses

- For hand washing to decrease bacteria on the skin.
- Recommended for repeated use.

Warnings

Flammable, keep away from fire or flame when using this product

For External Use Only

- Do not use in eyes.
- In case of eye contact, flush with water for 15 minutes.
- Discontinue use if irritation and redness develop. If condition persists for more than 72 hours consult a doctor.
- Avoid contact with broken skin.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions

- Wet hands thoroughly with product and allow to dry without wiping.

Other Information

For Spill/Exposure Emergency Response Service in English, French and Spanish (and 23 other languages), call CARECHEM 24 at 866-928-0789.

Inactive Ingredients

Acrylates/C10/30 Alkyl Acrylate Crosspolymer, EDTA, Fragrance, Glycerin, Purified Water and Tetrahydroxypropyl Ethylenediamine.

Questions?

Call 610-644-8335

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DECON-HAND®

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Lot Specific Sterile Documentation

(received with each shipment)

Certificate of Analysis
Certificate of Sterility
Certificate of Irradiation

(Please contact VAI for a sample of this documentation)



SCMD

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 unidose packages in ISO 5 (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. To learn more about our division capabilities please visit www.sterile.com

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