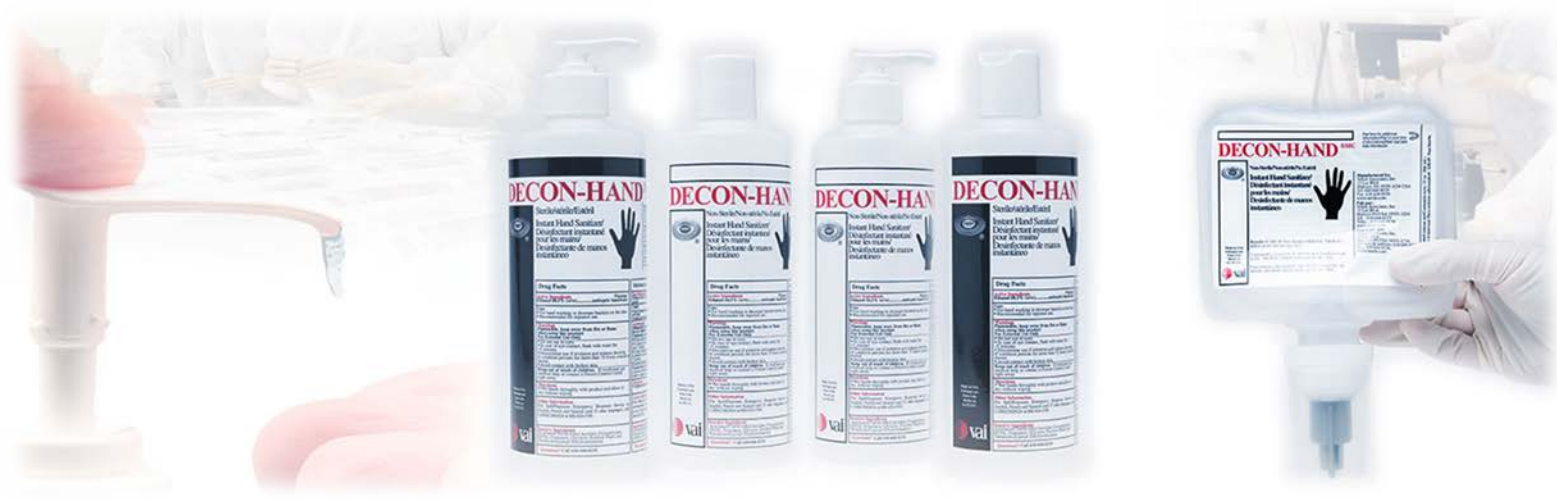
VELTEK ASSOCIATES, INC.

# 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
- Filed 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

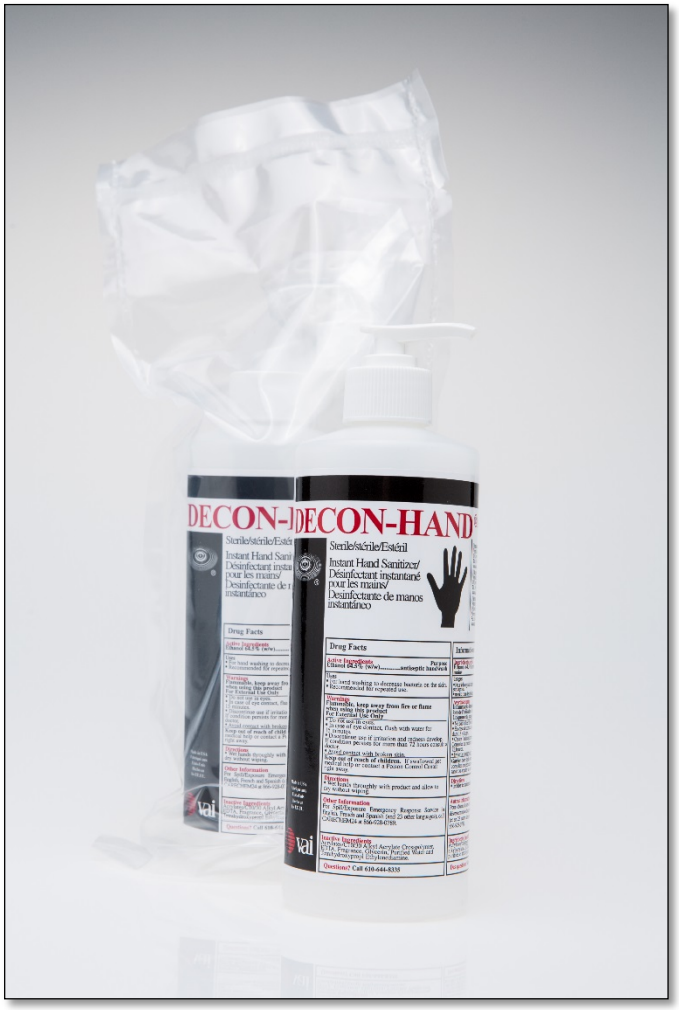
The DH-100 is an additional dispensing option for **DECON-HAND** 16 oz pump containers. VAI developed the DH-100 Dispenser to meet the requirements of cGMP cleanroom operations by reducing cross contamination and preventing overuse. The DH-100 can be mounted directly to the gowning room wall, is made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

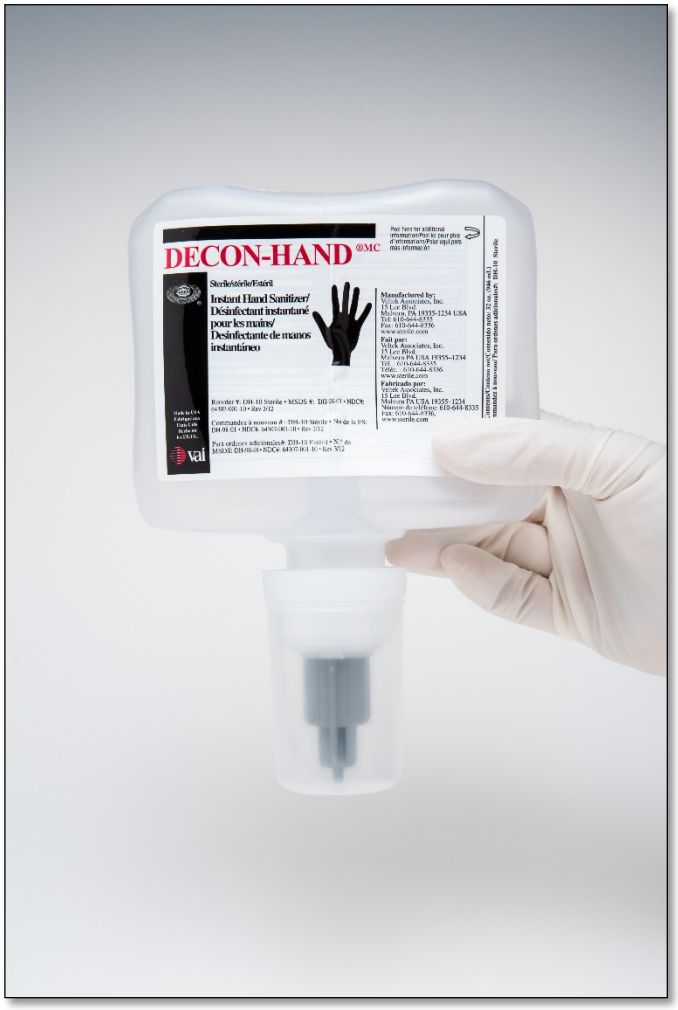
## 216-P Dispenser

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 |



# VAI's Product Label Colors

15 Lee Boulevard Malvern, PA 19355-1234 USA
Toll Free: 888.478.3745 T: 610.644.8335 www.sterile.com

## 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-Tranparent | 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 | | |

Rev. 06 June 2012

# DECON-HAND®

## FDA Registered Ethanol Based Hand Sanitizer

### 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:** **Purpose:**
Ethanol 64.5% (w/w)……..……..antiseptic hand wash

**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 Tetrahydroxypropul Ethylenediamine.

**Questions?**

**Call 610-644-8335**

# DECON-HAND®

**FDA Registered Ethanol Based Hand Sanitizer**

# 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