

DECON-HAND[®]

Instant Hand Sanitizer

HAND_VL-1401-3
Revised 19 November, 2013

Technical Data File



O V E R V I E W

DECON-HAND®

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DECON-HAND

FDA Registered Instant Hand Sanitizer

PRODUCT DESCRIPTION

VAI® manufactures an alcohol-based hand sanitizer that is processed to comply with the standards required by customers in the pharmaceutical, biotechnology, medical device and healthcare industries. DECON-HAND has multiple uses throughout any facility but also complies with the requirements for transport into classified areas. 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 an USA FDA registered product NDC# 64307-001. It is used primarily as an instant hand sanitizer before glove donning.

DECON-HAND is filled in ISO 5 (Grade A/B, former Class 100). It is filtered and subsequently gamma irradiated to 10⁻⁶ Sterility Assurance Level. It is available in 16oz bottles that can either be used with a hand pump or a wall-mounted dispensing system, as well as 32oz bottles that are costumed fit to the Asepti-Cleanse® Dispensing System offered by VAI. These DECON-Hand products are available in both sterile and non-sterile formulas. Each sterile container is packaged double bagged, and delivered with lot specific Certificate of Irradiation, Certificate of Analysis, and a Certificate of Sterility. DECON-HAND products are completely traceable and validated for sterility and shelf life. This product is available in the ABCD CLEANROOM INTRODUCTION SYSTEM.

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 a bag. Each bag acts as barrier protecting the finished product from viable and non-viable contamination. This prohibits the need for decontaminating the outer bag prior to entering a cleaner area. In this packaging system each container is individually packaged into two easy tear bags, and all the individually packaged containers are then placed into two liner bags.

ASEPTI-CLEANSE DISPENSING SYSTEM

PRODUCT DESCRIPTION

VAI® offers a hands-free dispensing system for DECON-HAND. The dispensing system is the most advanced infrared sensor dispensing system available in the pharmaceutical and biotechnology industries. Developed to meet the requirements of cGMP clean room operations, Asepti-Cleanse is sealed to protect the internal electronics against cleaning and disinfecting. The unit mounts directly to glass or walls, making the dispenser an excellent choice for gowning rooms or aseptic manufacturing areas. DECON-HAND is a mild alcohol formula with emollients for use on bare hands. It may also be used on clean room gloves.

ORDERING INFORMATION

Order#	Description	Qty/Cs
DH-04	DECON-HAND 16oz Non-Sterile	12
DH-06	DECON-HAND 16oz Sterile	12
DH-09	DECON-HAND Non-Sterile 32 oz Bottle for Asepti-Cleanse	12
DH-10	DECON-HAND Sterile 32oz Bottle for Asepti-Cleanse	12
DH-100	DECON-HAND Wall Dispenser (316L Stainless)	1
216-P	Push Pump for 16oz DECON-HAND Bottle	1
DEC-301	ASEPTI-CLEANSE Dispenser for 32 oz Bottles	1

Available Technical Data Supplements (Upon Request):

- Validation Report
- Specific Test Reports (Consult VAI)
- MSDS

Veltek Associates, Inc.

15 Lee Boulevard, Malvern, PA 19355-1234

Tel: (610)644-8335 • Fax: (610)644-8336 • E-mail: vai@sterile.com • VL-1401-3 • 19 November 2013

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SPECIFICATIONS

Specification

DECON-HAND

Appearance:	Clear Gel
Color:	Water Like
Clarity:	Clear
Physical State:	Liquid/Gel
Boiling Point:	173°F (78°C) (Of Ethyl alcohol)
Specific Gravity:	0.734
Flash Point:	70°F (21°C)
Oxidizing Properties:	None
Sensitivity to Static Discharge:	Yes
Odor:	Mild alcohol and citrus (Mild Ethanol)
Ethanol:	58.1-71.0%
pH:	6.0-8.0
Solubility (H2O):	Miscible
VOC:	65%
Flammability Class:	Class IB
Sensitivity to Mechanical Impact:	No
Viscosity:	5,000 to 30,000 cps

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PRODUCT LABELING

Any specific product label is available upon request.

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 15 LEE BOULEVARD MALVERN, PA 19355-1234 USA
TOLL FREE: 888.478.3745 T: 610.644.8335 WWW.STERILE.COM
VELTEK ASSOCIATES, INC.

VELTEK DECON PRODUCT LABEL COLORS

PRODUCT NAME	BOTTLE/CAN COLOR	LABEL BACKGROUND COLOR	BAR & USER INFO COLOR	TEXT COLOR
DECON-AHOL WFI FORMULA 70% AEROSOL	COOL GREY	PRINTED CAN COOL GREY		
DECON-AHOL WFI FORMULA 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	COOL GREY		
DECON-AHOL WFI FORMULA 70% SQUEEZE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI FORMULA 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-PHASE	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. 05 August 2013

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Product Information

Manufactured by:

Veltek Associates, Inc.

15 Lee Blvd. Malvern, PA 19355-1234 USA

Tel: 610-644-8335 Fax: 610-644-8336 www.sterile.com

Reorder Numbers: DH-04, DH-06, DH-09, DH-10

Drug Facts:

Active Ingredients: Ethanol 64.5% (w/w)

Purpose: antiseptic handwash

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 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 CARECHEM24 at 866-928-0789.

Inactive Ingredients:

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

NDC# 64307-001

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DECON-HAND

Sterile
Instant Hand Sanitizer
Sterile Pharmaceutical Clean Room Formula

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)

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INSTANT HAND-SANITIZER TESTING

DERMAL IRRITATION TEST

FHSA (Federal Hazardous Substances Control Act)

Primary Dermal Irritation Test in Rabbits

Primary Dermal Irritation Score: 1.0 (mild primary Irritant)

PRESERVATIVE EFFICACY TESTING

Antimicrobial Preservatives - Effectiveness (USP 23*) <51>

Conclusion, "Under the conditions of the investigation, the Alcohol Hand Sanitizer RDN66C (DECON-HAND) demonstrated to be an effective preservative system against bacteria and fungi according to USP 23 criteria.

AOAC AVAILABLE CHLORINE IN DISINFECTANTS

Official Methods of Analysis of the AOAC. 1 15th Ed, 1990, Chapter 6 Disinfectants, 955.16.

Conclusion: "Antiseptic Hand Wash, Formula RDA66C (DECON-HAND), Lot #0323-95, a ready-to-use product, demonstrated an available chlorine equivalent greater than the 200 ppm NaOCL standard control.

*at the time of registration

TIME-KILL STUDIES - See attached summary

Time-Kill Studies

Rev 12-04-97

Time Kill Study @ Viomed 1995

Organism	ATCC No.	Date	% Reduction 15 seconds	% Reduction 30 seconds	Same as on monograph?
<i>Staphylococcus aureus</i>	6538	10-6-95	>99.999	>99.999	Yes (1 other req.)
<i>Pseudomonas aeruginosa</i>	15442	10-6-95	>99.999	>99.999	Yes (1 other req.)
<i>Shigella dysenteriae</i>	13313	10-6-95	>99.999	>99.999	
<i>Salmonella typhi</i>	23564	10-6-95	>99.999	>99.999	
<i>Proteas vulgaris</i>	13315	10-6-95	>99.999	>99.999	
<i>Escherichia coli</i>	11229	10-6-95	>99.999	>99.999	Yes
MRSA	33552	10-6-95	>99.999	>99.999	
Herpes Simplex Virus Type I	VR-733	9-19-96	>99.999	>99.999	
Influenza A ₂	VR-544	9-19-95	>99.999	>99.999	
HIV-1	HTLV-IIIB	10-11-95	>99.9	>99.999	

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