

SANI-HANDS[®]

Instant Hand Sanitizing Wipes

SCIENTIFIC COMPENDIUM

NDC 10819-3917-1, 10819-3917-2, 10819-3916-1
(Sani-Hands[®] Instant Hand Sanitizing Wipes)

THE IMPORTANCE OF HAND HYGIENE IN THE HEALTHCARE SETTING

“In the United States, hospital patients get nearly 722,000 healthcare-associated infections each year. That’s about 1 infection for every 25 patients. Infections that patients get in the hospital can be life-threatening and hard to treat. Hand hygiene is one of the most important ways to prevent the spread of infections.”¹

Sani-Hands® Instant Hand Sanitizing Wipes are now compliant with SHEA/IDSA HAI Compendium for Hand Hygiene. SHEA/IDSA now states that alcohol-containing hand wipes are a convenient option for bed-bound patients, first responders, and others who cannot easily access soap and water.²

PRODUCT DESCRIPTION

Sani-Hands® Instant Hand Sanitizing Wipes are an ideal hand hygiene solution for healthcare workers, patients and visitors when soap and water are not available. Containing 70% Ethyl alcohol, Sani-Hands® wipes are a fast, effective hand sanitizer. Additionally, Sani-Hands® wipes are more effective at removing soil on the hands than gels alone.³

CHEMICAL COMPOSITION

Active Ingredients: Alcohol (Ethyl).....	70.00%
Inactive ingredients: (Water, Propylene glycol, Glycerin, Aloe barbadensis leaf juice, Tocopheryl acetate (Vitamin E)).....	30.00%
TOTAL: (Does not include the weight of the cloth).....	100.00%

EFFICACY: IN-VITRO TIME KILL STUDIES⁴

BACTERIA AND FUNGI STUDIES⁵

PURPOSE: To determine how rapidly and effectively Sani-Hands® wipes kill a variety of Gram negative and Gram positive bacteria within a 15 second exposure.

METHODOLOGY: Fluid from the wipe was expressed aseptically and transferred to sterile incubator tubes. The tubes were subsequently inoculated with the broth culture of the test microorganism containing up to 10⁸ CFU. After 15 seconds, the entire inoculated volume of Sani-Hands® formula was transferred to neutralizers. Serial dilutions were plated using standard plating techniques, and percent reductions for each organism were calculated after incubation.

CONCLUSION: Sani-Hands® wipes demonstrated to be effective at killing all microorganisms listed in 15 seconds after drying.

VIRAL STUDIES⁵

PURPOSE: To evaluate the antiviral properties of Sani-Hands® wipes when exposed to a virus (in suspension) for a 15 second exposure.⁶

METHODOLOGY: Fluid from the wipe was expressed aseptically and transferred to sterile tubes. The tubes were subsequently inoculated with the virus suspension and held for the 15 second exposure period. After the exposure period, a small aliquot was removed and assayed for presence of virus.

CONCLUSION: Sani-Hands® wipes demonstrated to be effective at killing all microorganisms listed in 15 seconds after drying.

¹ Centers for Disease Control and Prevention, <http://www.cdc.gov/hai>, accessed electronically September, 2014.

² Strategies to Prevent Healthcare-Associated Infections through Hand Hygiene. Infection Control and Hospital Epidemiology, Vol. 35, No. S2, A Compendium of Strategies to Prevent Healthcare-associated Infections in Acute care Hospitals: 2014 Updates (September 2014), pp. S155-S178.

³ HTR Study No. 04-123612-106, data on file, PDI, Orangeburg, New York.

⁴ **INDEPENDENT LABORATORIES:** Mycoscience Labs, Willington, CT, June 2004 • ATS Labs, Egan, MN: June 2004, December 2010, January 2011, March 2011, May 2011, June 2011, September 2011.

⁵ Clinical data is representative of Sani-Hands® (NDC #: 10819-50) 65.9% Ethyl Alcohol formulation.

⁶ When exposed to Herpes simplex virus type 1, Strain G, Human Coronavirus, Strain 229E, Influenza A virus, Strain Hong Kong, HIV-1 (AIDS virus), Rhinovirus type 16, Strain 11767, Rotavirus, Strain WA (University of Ottawa).

BACTERIAL ORGANISM EFFICACY

(15 SEC. EXPOSURE)

MULTI-DRUG RESISTANT BACTERIA

<i>Acinetobacter baumannii</i> , Multi-Drug Resistant [ATCC 19606]	> 99.999%
Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> (CA-MRSA) [NARSA NRS384] [Genotype USA 300]	> 99.999%
Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> (CA-MRSA) [NARSA NRS123] [Genotype USA 400]	> 99.999%
<i>Enterococcus faecalis</i> , Vancomycin Resistant (VRE) (Vancomycin, Streptomycin, Gentamicin Resistant) [ATCC 51575]	> 99.999%
<i>Enterococcus faecium</i> (Multi-Drug Resistant including Vancomycin) [ATCC 51559]	> 99.998%
ESBL Resistant <i>Escherichia coli</i> [ATCC BAA-196]	> 99.999%
<i>Klebsiella pneumoniae</i> - Carbapenem Resistant [ATCC BAA-1705]	> 99.999%
<i>Klebsiella pneumoniae</i> - NDM-1 Positive [CDC 1000527]	> 99.999%
<i>Staphylococcus aureus</i> - Methicillin Resistant (MRSA) [ATCC 33591]	> 99.999%
<i>Staphylococcus aureus</i> (MRSA, Vancomycin tolerant) [ATCC 700788]	> 99.999%

BACTERIA

<i>Bacillus megaterium</i> [ATCC 14581]	99.940%
<i>Campylobacter jejuni</i> [ATCC 29428]	> 99.999%
<i>Clostridium difficile</i> (vegetative) [ATCC 9689]	> 99.999%
<i>Corynebacterium diphtheriae</i> [ATCC 11913]	> 99.999%
<i>Enterobacter aerogenes</i> [ATCC 13048]	> 99.999%
<i>Escherichia coli</i> [ATCC 11229]	> 99.999%
<i>Escherichia coli</i> O157:H7 [ATCC 35150]	> 99.999%
<i>Escherichia coli</i> O111:H8 [ATCC BAA-184]	> 99.999%
<i>Klebsiella pneumoniae</i> [ATCC 13883]	> 99.999%
<i>Listeria monocytogenes</i> [ATCC 15313]	> 99.999%
<i>Proteus mirabilis</i> [ATCC 7002]	> 99.999%
<i>Proteus hauseri</i> (<i>vulgaris</i>) [ATCC 13315]	> 99.999%
<i>Pseudomonas aeruginosa</i> [ATCC 15442]	> 99.999%
<i>Salmonella choleraesuis</i> serotype <i>typhimurium</i> [ATCC 14028]	> 99.999%
<i>Serratia marcescens</i> [ATCC 14756]	> 99.999%
<i>Shigella sonnei</i> [ATCC 11060]	> 99.999%
<i>Staphylococcus epidermidis</i> (Coagulase-negative Staphylococci) [ATCC 12228]	> 99.999%
<i>Streptococcus pneumoniae</i> [ATCC 33400]	> 99.999%
<i>Streptococcus pyogenes</i> [ATCC 19615]	> 99.999%
<i>Vibrio parahaemolyticus</i> [ATCC 17802]	> 99.999%

VIRAL ORGANISM EFFICACY

(15 SEC. EXPOSURE)

ENVELOPED VIRUSES

Herpes simplex virus type 1, Strain G [ATCC VR-733]	> 99.999%
Human Coronavirus, Strain 229E [ATCC VR-740]	> 99.900%
Influenza A virus, Strain Hong Kong [ATCC VR-544]	> 99.999%
HIV-1 (AIDS virus) [Strain HTLV-III _B]	> 99.990%

NON-ENVELOPED VIRUSES

Rhinovirus type 16, Strain 11767 [ATCC VR-1126]	99.700%
Rotavirus, Strain WA (University of Ottawa)	> 99.999%

PATHOGENIC FUNGI EFFICACY

(15 SEC. EXPOSURE)

YEAST ORGANISM

<i>Candida albicans</i> [ATCC 14053]	> 99.999%
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MOLD ORGANISM

<i>Aspergillus flavus</i> [ATCC 9643]	> 99.992%
<i>Trichophyton mentagrophytes</i> [ATCC 9533]	> 99.993%

MOST PREVALENT PATHOGENS THAT CAUSE HAIs

- According to the CDC, the pathogens below are responsible for 77% of all Healthcare Associated Infections.⁷
- At 15 second exposure, Sani-Hands® wipes have shown efficacy against:⁸

RANK	TOP PATHOGENS	% REDUCTION AFTER 15 SECOND EXPOSURE TO SANI-HANDS® WIPES
1	<i>Clostridium difficile</i> ⁹	> 99.999%
2	<i>Staphylococcus aureus</i>	> 99.999%
3	<i>Klebsiella pneumoniae</i>	> 99.999%
4	<i>Escherichia coli</i>	> 99.999%
5	Enterococcus species	> 99.998% ¹⁰
6	<i>Pseudomonas aeruginosa</i>	> 99.999%
7	Candida species	> 99.999% ¹¹
8	Streptococcus species	> 99.999% ¹²
9	Coagulase-negative Staphylococcus species	> 99.999%
10	Enterobacter species	> 99.999% ¹³

E.S.K.A.P.E. PATHOGENS⁷

- The E.S.K.A.P.E. pathogens are gram positive and gram negative multi-drug resistant organisms most commonly associated with antimicrobial resistance¹⁴.
- At 15 second exposure, Sani-Hands® formula has shown efficacy against:⁸

E.S.K.A.P.E. PATHOGENS	% REDUCTION AFTER 15 SECOND EXPOSURE TO SANI-HANDS® WIPES
<i>E: Enterococcus faecium</i>	> 99.998%
<i>S: Staphylococcus aureus</i>	> 99.999%
<i>K: Klebsiella pneumoniae</i>	> 99.999%
<i>A: Acinetobacter baumannii</i>	> 99.999%
<i>P: Pseudomonas aeruginosa</i>	> 99.999%
<i>E: Enterobacter species</i>	> 99.999% ¹³

⁷ Antimicrobial-Resistant Pathogens Associated With Healthcare-Associated Infections: Annual Summary of Data Reported to the National Healthcare Safety Network at the Centers for Disease Control and Prevention, 2006–2007.

⁸ INDEPENDENT LABORATORIES: Mycoscience Labs, Willington, CT, June 2004 • ATS Labs, Egan, MN: June 2004, December 2010, January 2011, March 2011, May 2011, June 2011, September 2011.

⁹ Efficacy % shown is for *Clostridium difficile* (vegetative) [ATCC 9689].

¹⁰ Efficacy % shown is for *Enterococcus faecalis* and *Enterococcus faecium*.

¹¹ Efficacy % shown is for *Candida albicans*.

¹² Efficacy % shown is for *Streptococcus pneumoniae* [ATCC 33400] and *Streptococcus pyogenes* [ATCC 19615].

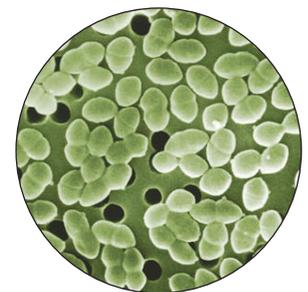
¹³ Efficacy % shown is for *Enterobacter aerogenes*.

¹⁴ Beucher, et al. Bad Bugs, No Drugs: No ESKAPE! An Update from the Infectious Disease Society of America, Clinical Infectious Disease, 2009:48.

MOST PREVALENT PATHOGENS BY HAI TYPE 15

The table below shows a ranking of the top pathogens associated with each HAI type, and the efficacy of Sani-Hands® wipes against each.

RANK	CLABSI CENTRAL LINE-ASSOCIATED BLOODSTREAM INFECTION	CAUTI CATHETER-ASSOCIATED URINARY TRACT INFECTION	VAP PNEUMONIA	SSI SURGICAL SITE INFECTION
	TOP 5 PATHOGENS	TOP 5 PATHOGENS	TOP 5 PATHOGENS	TOP 5 PATHOGENS
	% REDUCTION AFTER 15 SECOND EXPOSURE TO SANI-HANDS® WIPES ¹⁶	% REDUCTION AFTER 15 SECOND EXPOSURE TO SANI-HANDS® WIPES ¹⁶	% REDUCTION AFTER 15 SECOND EXPOSURE TO SANI-HANDS® WIPES ¹⁶	% REDUCTION AFTER 15 SECOND EXPOSURE TO SANI-HANDS® WIPES ¹⁶
1	Candida species > 99.999% ¹⁷	<i>Escherichia coli</i> > 99.999%	<i>Staphylococcus aureus</i> > 99.999%	<i>Staphylococcus aureus</i> > 99.999%
2	Coagulase-negative <i>Staphylococci</i> > 99.999%	<i>Klebsiella pneumoniae</i> > 99.998%	<i>Pseudomonas aeruginosa</i> > 99.999%	Enterococcus species > 99.999% ¹⁸
3	<i>Staphylococcus aureus</i> > 99.999%	Enterococcus species > 99.998% ¹⁸	<i>Klebsiella pneumoniae</i> > 99.998%	<i>Klebsiella pneumoniae</i> > 99.998%
4	Enterococcus species > 99.998% ¹⁸	<i>Pseudomonas aeruginosa</i> > 99.999%	Streptococcus species > 99.999%	<i>Escherichia coli</i> > 99.999%
5	<i>Escherichia coli</i> > 99.999%	Candida species > 99.999% ¹⁷	<i>Stenotrophomonas maltophilia</i> no data on file	Streptococcus species > 99.999%



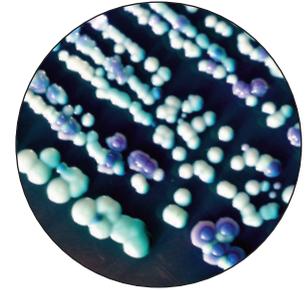
Enterococcus Species



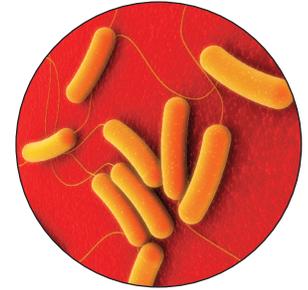
Klebsiella pneumoniae



Staphylococcus aureus



Candida species



Escherichia coli

¹⁵ Antimicrobial-Resistant Pathogens Associated With Healthcare-Associated Infections: Annual Summary of Data Reported to the National Healthcare Safety Network at the Centers for Disease Control and Prevention, 2006-2014.

¹⁶ INDEPENDENT LABORATORIES: Mycoscience Labs, Willington, CT, June 2004 • ATS Labs, Egan, MN: June 2004, December 2010, January 2011, March 2011, May 2011, June 2011, September 2011.

¹⁷ Efficacy % shown is for *Candida albicans*.

¹⁸ Efficacy % shown is for *Enterococcus faecalis* and *Enterococcus faecium*.

IN-VIVO STUDIES¹⁹

For a copy of relevant published studies, please contact your local PDI sales representative.

EFFICACY OF ALCOHOL-BASED HAND SANITIZERS (ABHS): A HAND WIPE (65.9% ETHANOL) EXCEEDS THE KILLING CAPACITY OF A GEL RUB (62% ETHANOL)²⁰

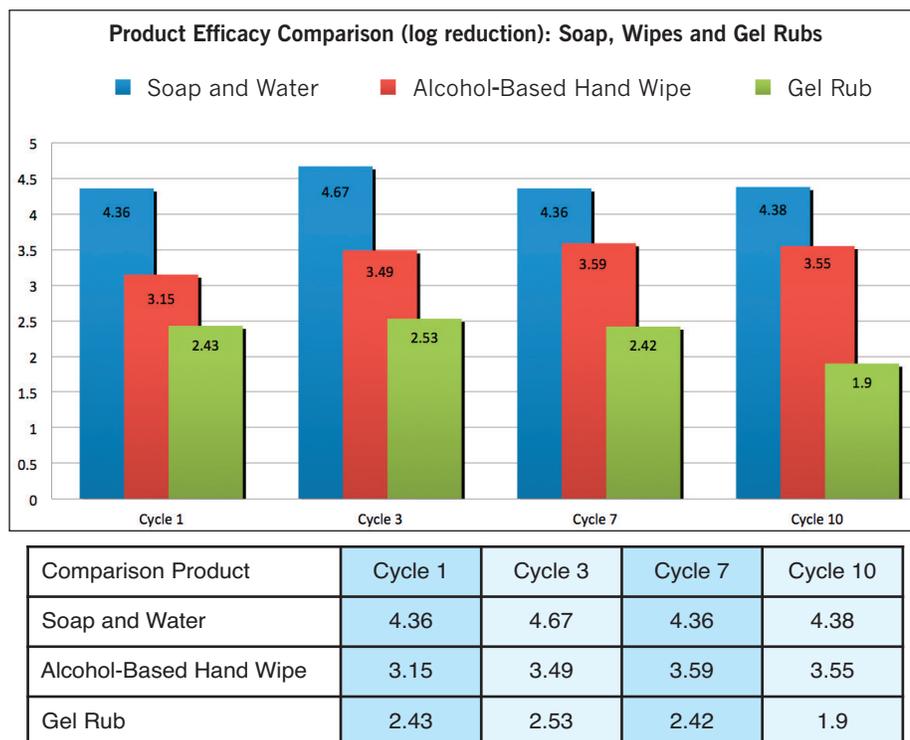
BACKGROUND: Decontamination of hands is accomplished by hand washing with soap or by use of waterless hand sanitizers. In 2002, the CDC stated that alcohol-based hand wipes were not an effective substitute for alcohol-based hand rubs or washing hands with an antimicrobial soap and water. This recommendation was based upon the use of alcohol-impregnated wipes with 30% vol/vol., which is 50% less than the alcohol content currently used in ABHS wipes.

OBJECTIVE: The objective of this study was to determine whether an alcohol gel hand wipe with 65.9% ethanol is as effective as a 62% ethanol hand rub or antimicrobial soap in removing bacteria from hands.

METHODOLOGY: In accordance with the method cited in the Federal Register Vol. 59 No. 116 Section 333.470, the hands of seven subjects were inoculated with a suspension of *Serratia marcescens*. Subjects washed with each of three different products with an interval of time separating each product usage. The products included the Sani-Hands® ALC hand wipe (65.9% ethanol) (PDI, Inc.), Purell® gel rub (62% ethanol) (GOJO®), and Kindest Kare® antimicrobial soap (0.75% Triclosan) (Steris®, Corp). The products were used according to manufacturer's instructions and a standard hand washing technique was employed for use of antimicrobial soap and water. Recovery of viable bacteria after product usage/washing was performed using the Glove Juice recovery method. The recovery liquid was plated on TSA and enumerated after test cycles 1, 3, 7 and 10.

RESULTS: 56 observations were analyzed. Significantly greater log reduction of *S. marcescens* was observed for the hand wipe (65.9% ethanol) compared to the gel rub (62% ethanol) (p , 0.001). The mean log reductions [Std. dev.] for the hand wipe, gel rub and soap were 3.44 [0.847], 2.32 [1.065], and 4.44 [1.018] respectively. The mean log reductions decreased over time for the gel rub, but not for the hand wipe. Only the gel rub showed decreased efficacy (log reduction from baseline) between cycles 7 and 10 (log 2.42 vs. 1.90). As expected, hand-washing with antimicrobial soap was more effective than either of the 2 alcohol-based hand sanitizers.

CONCLUSION: The use of alcohol-based hand sanitizers by patients and healthcare providers effectively reduces hand carriage of potential pathogens. The hand wipe (65.9% ethanol) was significantly more effective than the gel rub (62% ethanol) in reducing the number of viable bacteria on the hands. Additional studies are underway to determine the comparative efficacy of these products for removal of spore-forming bacteria.



¹⁹ Clinical data is representative of Sani-Hands® (NDC #: 10819-50) 65.9% Ethyl Alcohol formulation vs. the Purrell (NDC #: 21749 515) 62% Ethyl Alcohol formulation.

²⁰ Stout, JE. Efficacy of Alcohol-Based Hand Sanitizers (ABHS): A Hand Wipe (65.9% Ethanol) Exceeds the Killing Capacity of a Gel Rub (62% Ethanol). American Journal of Infection Control, Nov 2010.

IN-VIVO STUDIES CONTINUED²¹

HEALTH CARE PERSONNEL HANDWASH STUDY USING SOILED HANDS²²

PURPOSE: To demonstrate the functionality of mechanical wiping relative to microbial reduction on heavily soiled hands.

METHODOLOGY: The protocol used in this study is based on the procedures prescribed in the 1994 FDA tentative final monograph for a health care personnel handwash (Federal Register, Vol. 59, pp. 31402-31452, June 17, 1994). This procedure was modified to assess the effects of heavily soiled hands by using raw beef with a Gram negative bacteria (*E. coli*) count of at least 10^6 CFU/gram. Sani-Hands® formula was tested against a rub-in handwash gel and a non-active control (wipe, wet with sterile water). Each subject followed a treatment procedure aligned with label use instructions.

CONCLUSION: The performance criteria defined in the 1994 FDA Tentative Final Monograph, in part, requires that a product achieve at least a $2.0 \log_{10}$ reduction in a marker organism after the first treatment application. Sani-Hands® wipes achieved a $>2.0 \log_{10}$ reduction after a single hand treatment, thus exceeding FDA efficacy performance criteria specified for the initial treatment. The data below (Chart 1) suggests that the superior performance of Sani-Hands® wipes is enhanced by the physical removal of soil and bacteria by the wipe. The results of the non-active control clearly demonstrate that physical wiping is functional in reducing microbial population. Even without the presence of an antimicrobial, the non-active control achieved nearly a $2 \log_{10}$ reduction. The data further suggests that, with the rub-in alcohol handwash gel, there is a significant disadvantage in microbial reduction without the benefit of wiping action.

PRODUCT	LOG ₁₀ REDUCTION
Sani-Hands® ALC (alcohol gel wipe)	2.70
Non-Active Control (wipe, wet with sterile water)	1.95
Rub-In Alcohol Handwash Gel	1.57

HEALTH CARE PERSONNEL HANDWASH STUDY²³

PURPOSE: To determine the ability of Sani-Hands® wipes to reduce transient microbial flora when used in a hand treatment procedure with marker organism, *Serratia marcescens* [ATTC No. 14752].

METHODOLOGY: The protocol used in this study is based on the procedures prescribed in the 1994 FDA Tentative Final Monograph for healthcare personnel handwash (Federal Register Vol. 59, pp. 31402-31452, June 17, 1994). The required procedure is a modification of ASTM E-1174-94. Each subject followed a treatment procedure aligned with label use instructions.

CONCLUSION: Sani-Hands® wipes achieved a $>2.0 \log_{10}$ reduction after a single hand treatment, thus exceeding FDA efficacy performance criteria for the initial treatment.

²¹ Clinical data is representative of Sani-Hands® (NDC #: 10819-50) 65.9% Ethyl Alcohol formulation vs. the Purrell (NDC #: 21749 515) 62% Ethyl Alcohol formulation.

²² HTR Study No. 04-123612-106, Data on file, PDI, Orangeburg, New York.

²³ HTR Study No. 04-123526-106, Data on file, PDI, Orangeburg, New York.

SAFETY²⁴

REPEATED INSULT PATCH TEST²⁵

PURPOSE: To determine the dermal irritation and sensitization potential of Sani-Hands® wipes.

METHODOLOGY: Study was conducted using 216 subjects. The induction phase involved repeated exposure of the product at the same site on each subject three times a week for a total of nine applications. Ten to fourteen days after induction, a challenge watch was applied to a virgin site on each subject for 24 hours. After 24 hours, the patch was removed and the site was evaluated for dermal irritation.

CONCLUSION: Use of Sani-Hands® wipes demonstrated minimal or no reaction which would cause dermal irritation or sensitization.

SAFETY IN-USE²⁶

PURPOSE: To evaluate the dermal irritation potential of Sani-Hands® formula under exaggerated use conditions following 25 repeated uses.

METHODOLOGY: A total of 25 human subjects completed the study. Each subject used one wipe on both hands for approximately 30 seconds. This was repeated 25 times with 5 minute intervals between uses. Subjects hands were evaluated at the end of 25 uses.

CONCLUSION: Use of Sani-Hands® wipes did not demonstrate any potential for eliciting dermal irritation in any of the 25 human subjects.

OTHER INFORMATION AND TESTING²⁴

SKIN MOISTURIZATION²⁷: Sani-Hands® wipes were clinically proven to hydrate the skin after repeated use. Sani-Hands® formula contains several emollients, such as, glycerine, propylene glycol, Aloe and Vitamin E acetate to promote moisturization of skin and help minimize the drying effects of alcohol.

FDA FOOD CODE COMPLIANT: meets the Food and Drug Administration (FDA) Food Code, Section 2-301.16.

OSHA BLOODBORNE PATHOGEN STANDARD 29 CFR PART 1910.1030: Meets the specific handwashing standard 1910.1030 (d)(2)(iv).

CHG COMPATIBILITY²⁸: A laboratory study was conducted to determine the effects of Chlorhexidine Gluconate (CHG) when combined directly with the Sani-Hands® solution. The study was based on the equivalent of using ten applications of Sani-Hands® wipes and one application of a 3.0% CHG product. Results showed that Sani-Hands® wipes did not cause significant reduction of percent CHG, and would therefore, not adversely affect the persistent activity of CHG containing products.

GLOVE USE: It is recommended to allow hands to dry completely after using Sani-Hands® wipes prior to applying gloves.

SHELF LIFE²⁹: Internal stability studies were conducted for purposes of establishing an expiration date for the unopened product. Current stability data supports a two year expiration period from date of manufacture.

WARNINGS:

- Flammable, keep away from fire or flame.
- For external use only.
- Do not use in or contact the eyes.
- Discontinue use if irritation and redness develop.
- If condition persists for more than 72 hours consult a physician.
- Keep out of reach of children, unless under adult supervision.

²⁴ Clinical data is representative of Sani-Hands® (NDC #: 10819-50) 65.9% Ethyl Alcohol formulation.

²⁵ CRL 81804 and CRL 30204-1, Data on file, PDI, Orangeburg, New York.

²⁶ Safety In Use test (CRL 30304), Data on file, PDI, Orangeburg, New York.

²⁷ Skin Moisturization (CRL 146007), Data on File, PDI, Orangeburg, New York.

²⁸ CHG Compatibility (9/1/04), Data on file, PDI, Orangeburg, New York.

²⁹ Shelf Life (Marketed stability program, PDI QC department), Data on file, PDI, Orangeburg, New York.