PROFESSIONAL BRAND

SANI-HANDS™

Made with TENCEL®

technical data bulletin

PRODUCT DESCRIPTION

Nonwoven cloth saturated with ethyl alcohol gel solution for the antiseptic cleansing of hands. Solution and towel are fragrance-free and dye-free.

CHEMICAL COMPOSITION

Active Ingredients

1. Active Ingredients:
   Alcohol (Ethanol).....65.9% by volume

Inactive Ingredients

Water, Propylene glycol, Glycerin, Aloe barbadensis leaf juice, Tocopheryl acetate (Vitamin E)

EFFICACY

IN-VITRO TIME KILL STUDIES

Purpose – To determine how rapidly and effectively Sani-Hands® killed a variety of Gram negative and Gram positive micro-organisms including spore forming bacteria at 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 each test microorganism containing up to 10^8 CFU. After 15 seconds, the entire inoculated volume of Sani-Hands® 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® demonstrated to be very effective at killing all 30 microorganisms listed inside in 15 seconds (see Chart 1, page 2).

Independent Laboratory: Mycoscience Labs, Willington, CT: June 28, 2004

PROFESSIONAL®

wipe your world clean℠

SANI-HANDS™

VIRAL STUDIES*

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

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 – In the presence of 5% fetal bovine serum, Sani-Hands® demonstrated a greater than 99% reduction in viral titer after the 15-second exposure period against the viruses listed (see Chart 2).

Independent Laboratory: ATS Labs, Eagan, MN: June 28, 2004

IN-VIVO

HEALTHCARE PERSONNEL HANDWASH STUDY USING SOILED HANDS

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 healthcare 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® was tested against a rub-in alcohol 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® achieved >2.0 $\log_{10}$ reduction after a single hand treatment, thus exceeding FDA efficacy performance criteria specified for the initial treatment. The data at right (Chart 3) suggests that the superior performance of Sani-Hands® 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

CHART 1: Percent Reduction After 15-Second Exposure

Microorganism	Classification	ATCC#	% Reduction
Acinetobacter baumanii, (multi-drug resistant)	Gram negative rod	19606	>99.999
Aspergillus flavus	fungi (mold)	9643	=99.999
Bacillus megaterium	Gram positive bacteria	14581	>99.999
Campylobacter jejuni	Gram negative rod	29428	>99.999
Candida albicans	fungi (yeast)	14053	>99.999
Clostridium difficile	Gram positive bacteria	9689	>99.998
Corynebacterium diptheriae	Gram positive rod	11913	>99.999
Enterobacter aerogenes	Gram negative rod	13048	>99.999
Enterococcus faecium (multi-drug resistant including Vancomycin)	Gram positive cocci	51559	>99.999
Enterococcus faecalis (Vancomycin, Streptomycin, and Gentamicin resistant)	Gram positive cocci	51575	>99.999
Escherichia coli (ESBL producing, (multi-drug resistant, derived from clinical isolate, Klebsiella pneumoniae ATCC #14714)	Gram negative rod	BAA-196	>99.999
Escherichia coli	Gram negative rod	11229	>99.999
Escherichia coli (0157:H7)	Gram negative rod	35150	>99.999
Escherichia coli (0111:H8)	Gram negative rod	BAA-184	>99.999
Klebsiella pneumoniae	Gram negative rod	13883	>99.99
Klebsiella pneumoniae (carbapenem resistant)	Gram negative rod	BAA-1705	>99.999
Listeria monocytogenes	Gram positive rod	15313	>99.999
Proteus mirabilis	Gram negative rod	7002	>99.999
Proteus hauseri (vulgaris)	Gram negative rod	13315	>99.999
Pseudomonas aeruginosa	Gram negative rod	15442	>99.999
Salmonella choleraesuis serotype typhimurium	Gram negative rod	14028	>99.999
Serratia marcescens	Gram negative rod	14756	>99.999
Shigella sonnei	Gram negative rod	11060	>99.999
Staphylococcus aureus (MRSA)	Gram positive cocci	33591	>99.999
Staphylococcus aureus (MRSA, Vancomycin tolerant)	Gram positive cocci	700788	>99.999
Staphylococcus epidermidis	Gram positive cocci	12228	>99.999
Streptococcus pneumoniae	Gram positive cocci	33400	>99.999
Streptococcus pyogenes	Gram positive cocci	19615	>99.999
Trichophyton mentagrophytes	fungi (mold)	9533	>99.999
Vibrio parahaemolyticus	Gram negative rod	17802	>99.999

CHART 2: Percent Reduction After 15-Second Exposure

Virus	ATCC#	% Reduction
Herpes simplex virus type 1, Strain F(1)	VR-733	>99.000
Human Coronavirus, Strain 229E	VR-740	>99.000
Influenza A virus, Strain Hong Kong	VR-544	>99.000
Rhinovirus type 16, Strain 11757	VR-1126	>99.000
HIV-1 (AIDS Virus) Strain HTLV-III$_B$	—	>99.990
Rotavirus, Strain WA (University of Ottowa)	—	>99.000

** The 1994 FDA Tentative Final Monograph does not comment on viral efficacy of hand hygiene products.*

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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.

Independent Laboratory: Hill Top Research, Inc., Miamiville, OH: November 30, 2004

HEALTHCARE PERSONNEL HANDWASH STUDY

Purpose – To determine the ability of Sani-Hands® to give reduction of transient microbial flora when used in a hand treatment procedure with marker organism, *Serratia marcescens* ATCC 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® achieved >2.0 $\log_{10}$ reduction after a single hand treatment, thus exceeding FDA efficacy performance criteria for the initial treatment.

Independent Laboratory: Hill Top Research, Inc., Miamiville, OH: September 30, 2004

SAFETY

REPEATED INSULT PATCH TEST

Purpose – To determine the dermal irritation and sensitization potential of Sani-Hands.®

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 14 days after induction, a challenge patch 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 – Sani-Hands® demonstrated minimal or no reaction which would cause dermal irritation or sensitization.

Independent Laboratory: Clinical Research Laboratories, Piscataway, NJ: June 11, 2004

CHART 3: Results from Health Care Personnel Handwash Study Using Soiled Hands

SAFETY IN-USE

Purpose – To evaluate the dermal irritation potential of Sani-Hands® 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 – Sani-Hands® did not demonstrate any potential for eliciting dermal irritation in any of the 25 human subjects.

Independent Laboratory: Clinical Research Laboratories, Piscataway, NJ: May 13, 2004

SANI-HANDS™

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OTHER INFORMATION & TESTING

Skin Moisturization

Sani-Hands® contains several emollients, such as, glycerin, propylene glycol, aloe and Vitamin E acetate to promote moisturization of skin and help minimize the drying effect of alcohol.

OSHA Bloodborne Pathogen Standard 29 CFR Part 1910.1030

Meets the specific handwashing standard 1910.1030 (d)(2)(iv).

FDA Food Code Compliant

Meets the Food and Drug Administration (FDA) Food Code, Section 2-301.16.

CHG Compatibility

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® and one application of a 3.0% CHG product. Results showed that Sani-Hands® 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® prior to applying gloves.

Shelf Life

FDA-OTC stability was 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.

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ISO 9001:2000 certified

Orangeburg, NY

wipeyourworldclean.com