



# HANDS Instant Sanitizing Wipes



## PRODUCT DESCRIPTION

**Sani Professional®** Hands Instant Sanitizing Wipes are nonwoven cloth saturated with an ethyl alcohol solution for the antimicrobial cleansing of hands. Solution and towel are fragrance free and dye free.



**FIND IT IN OUR NEW, COLOR-CODED PACKAGE:  
“BLUE FOR HANDS”.**

## CHEMICAL COMPOSITION/PRODUCT DATA:

Active Ingredients: Alcohol (Ethanol)	65.9% (by volume)
Inactive Ingredients: Water, Propylene glycol, Glycerin, Aloe barbadensis leaf juice, Tocopheryl acetate (Vitamin E)	34.1%
<b>Total</b>	<b>100.00%</b>

(Does not include weight of the wipe)



## EFFICACY STUDIES

## IN-VITRO TIME KILL STUDIES

## Bacterial Studies

**Purpose** – To determine how rapidly and effectively Sani Professional® Hands Instant Sanitizing Wipes killed a variety of Gram negative and Gram positive microorganisms after 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<sup>8</sup> CFU/ml. After 15 seconds, the entire inoculated volume of Sani Professional® Hands Instant Sanitizing Wipes was transferred to neutralizers. Serial dilutions were plated using standard plating techniques and percent reductions for each organism were calculated after incubation.

**Conclusion** – Sani Professional® Hands Instant Sanitizing Wipes proved to be effective at killing all 30 microorganisms listed within a 15 second exposure.

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

Chart 1: Percent Reduction After 15-Second Exposure

Microorganism	Classification	ATCC#	% Reduction
<i>Acinetobacter baumannii</i> , (multi-drug resistant)	Gram negative rod	19606	>99.999
<i>Aspergillus flavus</i>	fungi (mold)	9643	= 99.999
<i>Bacillus megaterium</i>	Gram positive rod	14581	>99.999
<i>Campylobacter jejuni</i>	Gram negative rod	29428	>99.999
<i>Candida albicans</i>	fungi (yeast)	14053	>99.999
<i>Clostridium difficile</i> (vegetative)	Gram positive rod	9689	>99.998
<i>Corynebacterium diphtheriae</i>	Gram positive rod	11913	>99.999
<i>Enterobacter aerogenes</i>	Gram negative rod	13048	>99.999
<i>Enterococcus faecium</i> (multi-drug resistant including Vancomycin)	Gram positive cocci	51559	>99.999
<i>Enterococcus faecalis</i> (Vancomycin, Streptomycin, and Gentamicin resistant)	Gram positive cocci	51575	>99.999
<i>Escherichia coli</i> (ESBL producing, multi-drug resistant, derived from clinical isolate, Klebsiella pneumoniae ATCC #14714)	Gram negative rod	BAA-196	>99.999
<i>Escherichia coli</i>	Gram negative rod	11229	>99.999
<i>Escherichia coli</i> (O157:H7)	Gram negative rod	35150	>99.999
<i>Escherichia coli</i> (O111:H8)	Gram negative rod	BAA-184	>99.999
<i>Klebsiella pneumoniae</i>	Gram negative rod	13883	>99.99
<i>Klebsiella pneumoniae</i> (carbapenem resistant)	Gram negative rod	BAA-1705	>99.999
<i>Listeria monocytogenes</i>	Gram positive rod	15313	>99.999
<i>Proteus mirabilis</i>	Gram negative rod	7002	>99.999
<i>Proteus hauseri</i> (vulgaris)	Gram negative rod	13315	>99.999
<i>Pseudomonas aeruginosa</i>	Gram negative rod	15442	>99.999
<i>Salmonella choleraesuis</i> serotype typhimurium	Gram negative rod	14028	>99.999
<i>Serratia marcescens</i>	Gram negative rod	14756	>99.999
<i>Shigella sonnei</i>	Gram negative rod	11060	>99.999
<i>Staphylococcus aureus</i> (MRSA)	Gram positive cocci	33591	>99.999
<i>Staphylococcus aureus</i> (MRSA, Vancomycin tolerant)	Gram positive cocci	700788	>99.999
<i>Staphylococcus epidermidis</i>	Gram positive cocci	12228	>99.999
<i>Streptococcus pneumoniae</i>	Gram positive cocci	33400	>99.999
<i>Streptococcus pyogenes</i>	Gram positive cocci	19615	>99.999
<i>Trichophyton mentagrophytes</i>	fungi (mold)	9533	>99.999
<i>Vibrio parahaemolyticus</i>	Gram negative rod	17802	>99.999

**EFFICACY STUDIES**

**IN-VITRO TIME KILL STUDIES**

**Viral Studies**

**Purpose** – To evaluate the antiviral properties of Sani Professional® Hands Instant Sanitizing Wipes 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 Professional® Hands Instant Sanitizing Wipes 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*

**Chart 2: Percent Reduction After 15-Second Exposure**

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

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



**Kills Top Foodborne Pathogens**

Sani Professional® Hands Instant Sanitizing Wipes has been proven effective against the following foodborne pathogens:

**BACTERIA & COMMON SYMPTOMS:**

**SOURCES:**

***Campylobacter jejuni*\* ATCC# 29428**  
Diarrhea, abdominal cramps, fever, and vomiting; diarrhea may be bloody.

Raw or undercooked poultry, unpasteurized (raw) milk, contaminated drinking water

***Escherichia coli (O157:H7)\* ATCC# 35150***

***Escherichia coli*\*(ESBL producing, multi-drug resistant, derived from clinical isolate, *Klebsiella pneumoniae* ATCC#14714) ATCC# BAA-196**

Undercooked ground beef, unpasteurized (raw) milk or juice, soft cheeses made from raw milk, and raw fruits and vegetables (such as sprouts)

***Escherichia coli*\* ATCC# 11229**

***Escherichia coli (O111:H8)\* ATCC# BAA-184***

Severe diarrhea that is often bloody, severe abdominal pain, and vomiting

***Shigella sonnei*\* ATCC# 11060**

Diarrhea (often bloody), fever, and stomach cramps

Raw produce, contaminated drinking water, uncooked foods and cooked foods that are not reheated after contact with an infected food handler

***Listeria monocytogenes*\* ATCC# 15313**

Fever, stiff neck, confusion, weakness, vomiting, sometimes preceded by diarrhea

Ready-to-eat deli meats and hot dogs; refrigerated pâtés or meat spreads; unpasteurized (raw) milk and dairy products; soft, unpasteurized cheeses (e.g., queso fresco, Feta, Brie, Camembert); refrigerated smoked seafood; raw sprouts

***Salmonella choleraesuis serotype typhimurium*\* ATCC# 14028**

Diarrhea, fever, abdominal cramps, vomiting

Eggs, poultry, meat, unpasteurized (raw) milk or juice, cheese, contaminated raw fruits and vegetables

***Vibrio parahaemolyticus*\* ATCC# 17802**

Vomiting, diarrhea, abdominal pain, bloodborne infection. Fever, bleeding within the skin, ulcers requiring surgical removal

Undercooked or raw seafood, such as shellfish (especially oysters)

\*99.999% reduction of the microorganisms achieved within 15 seconds

Source: [www.cdc.gov/foodsafety](http://www.cdc.gov/foodsafety)



## EFFICACY STUDIES

### IN-VIVO STUDIES\*\*

#### Handwash Study Using Soiled Hands From Raw Beef

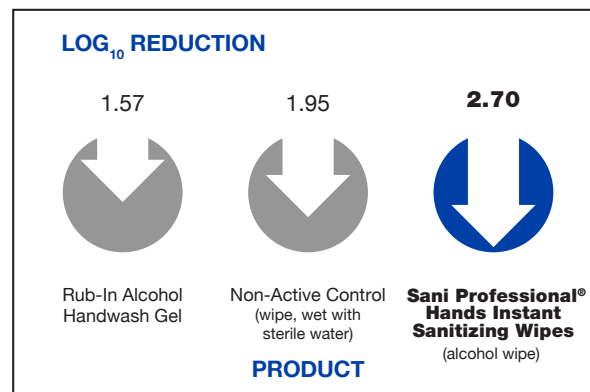
**Purpose** – To demonstrate the functionality of mechanical wiping relative to microbial reduction on heavily soiled hands.

**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<sup>6</sup> CFU/gram. Sani Professional® Hands Instant Sanitizing Wipes 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<sub>10</sub> reduction in a marker organism after the first treatment application. Sani Professional® Hands Instant Sanitizing Wipes achieved >2.0 log<sub>10</sub> reduction after a single hand treatment, thus exceeding FDA efficacy performance criteria specified for the initial treatment. The data suggests that the superior performance of Sani Professional® Hands Instant Sanitizing 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<sub>10</sub> 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.

#### Handwipe Exceeds The Killing Capacity Of Gel Rubs

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



#### Healthcare Personnel Handwash Study

**Purpose** – To determine the ability of Sani Professional® Hands Instant Sanitizing Wipes 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 Professional® Hands Instant Sanitizing Wipes achieved >2.0 log<sub>10</sub> 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

## ADDITIONAL INFORMATION AND TESTING

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### SAFETY

#### Repeated Insult Patch Test

**Purpose** – To determine the dermal irritation and sensitization potential of Sani Professional® Hands Instant Sanitizing 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 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 Professional® Hands Instant Sanitizing Wipes demonstrated minimal or no reaction which would cause dermal irritation or sensitization.

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

### SAFETY IN USE

#### Repeated Insult Patch Test

**Purpose** – To evaluate the dermal irritation potential of Sani Professional® Hands Instant Sanitizing Wipes 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 Professional® Hands Instant Sanitizing Wipes 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

### FOODSERVICE INFORMATION AND TESTING

#### FDA Food Code Compliant

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

#### NSF Nonfood Compounds Registration #151433 Category E3

This product is acceptable for use as a hand sanitizing product in and around food processing areas.

#### Kills Top Foodborne Pathogens

Tested 99.999% effective in 15 seconds against *Campylobacter jejuni*, *Escherichia coli* (O157:H7), *Listeria monocytogenes*, *Salmonella choleraesuis* serotype typhimurium, *Shigella sonnei* and *Vibrio parahaemolyticus*.

## OTHER INFORMATION AND TESTING

### Skin Moisturization

Sani Professional® Hands Instant Sanitizing Wipes 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.

*Independent Laboratory: Clinical Research Laboratories, Inc., Piscataway NJ, December 17, 2007*

### OSHA Bloodborne Pathogen Standard 29 CFR Part 1910.1030

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

### CHG Compatibility

A laboratory study was conducted to determine the effects of Chlorhexidine Gluconate (CHG) when combined directly with the Sani Professional® Hands Instant Sanitizing Wipes solution. The study was based on the equivalent of using ten applications of Sani Professional® Hands Instant Sanitizing Wipes and one application of a 3.0% CHG product. Results showed that Sani Professional® Hands Instant Sanitizing 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 Professional® Hands Instant Sanitizing Wipes 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.

Made in USA with domestic  
and imported materials

## PRECAUTIONARY STATEMENTS

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.

## #WinThisFoodFight

At Sani Professional®, we believe the battle against foodborne illness is a serious one. 1 in 6 Americans get sick from eating contaminated food, over 100,000 people are hospitalized and as many as 3,000 die as a result of foodborne illness.<sup>1</sup>

Sani Professional® can help you maintain a clean and safe facility to prevent cross contamination that could result into a foodborne outbreak. With our products, you can expect a consistent, predictable and effective experience. We care about food safety, just like you. Together, we can win the fight against foodborne illness.

<sup>1</sup> <https://www.cdc.gov/foodborneburden/index.html>