Kimberly-Clark® Professional

INSTANT HAND SANITIZER

Technical Bulletin
April 2001

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KIMBERLY-CLARK® Instant Hand Sanitizer

Kills Germs Without Soap and Water

KIMBERLY-CLARK® Instant Hand Sanitizer kills 99.9% of germs in as little as 15 seconds, without using soap and water.

- Broad spectrum, fast-acting antimicrobial effect
- Convenient and effective
- Non-toxic
- Meets FDA guidelines as safe for indirect food contact use
- Dermatologist tested
- Latex glove compatible
- Easy to apply
- Meets the protocol for a health care personnel hand wash

Appropriate For Use In:

- *Food Processing*
- *Meat & Poultry Processing*
- *Health Care Facilities*
- *And more ...*

Indications

Convenient and effective hand sanitizing when soap and water are not available. Use to supplement routine soap and water hand washing to reduce bacteria on the skin.

Appropriate in settings where soap and water are not readily available or convenient.

Meets the requirements of the CDC Guidelines for Hand Washing and Hospital Environmental Control (Category III).

Usage Instructions

Apply a thumbnail size amount to the hands and forearms. Rub in briskly. Do not rinse.

Does not require water or towels.

Physical Characteristics

Active Ingredient:	62% Ethyl Alcohol
Color:	Clear
Fragrance:	Light Citrus
pH:	7.0
Viscosity:	20,000 cps

DIN

02243379

Antimicrobial Efficacy *in vitro:* Time Kill Study

Gram Positive Bacteria	ATCC#	% Reduction 15 Seconds	% Reduction 30 Seconds	% Reduction 60 Seconds
Bacillus subtilis	19659	99.99	99.99	99.99
Micrococcus luteus	7468	99.96	99.99	99.87
Staphylococcus aureus	29213	99.99	99.99	99.99
Staphylococcus aureus (MRSA)	33592	99.99	99.99	99.99
Staphylococcus epidermidis	12228	99.99	99.99	99.98
Staphylococcus haemolyticus	29970	99.95	99.99	99.99
Staphylococcus hominis	27844	99.97	99.99	99.99
Staphylococcus saprophyticus	15305	99.99	99.99	99.99
Streptococcus pneumoniae	6303	99.99	99.99	99.99
Streptococcus pyogenes	19615	99.99	99.99	99.99
Gram Negative Bacteria				
Acinetobacter Iwoffii	15309	99.99	99.99	99.99
Bacteroides fragilis	23745	99.99	99.99	99.99
E. coli 0157:H7	43895	99.99	99.99	99.99
E. coli	11229	99.75	99.93	99.99
E. coli	25922	99.99	99.99	99.99
Enterobacter aerogenes	13048	99.73	99.99	99.99
Enterococcus faecalis	29212	99.99	99.99	99.99
Enterococcus faecalis (MDR) (VRE)	51299	99.99	99.99	99.99
Enterococcus faecium	19434	99.89	99.99	99.99
Haemophilus influenzae	19418	99.99	99.99	99.99
Klebsiella pneumoniae	10031	99.94	99.99	99.99
Proteus mirabilis	7002	99.99	99.99	99.99
Pseudomonas aeruginosa	15442	99.98	99.99	99.99
Pseudomonas aeruginosa	27853	99.99	99.99	99.99
Salmonella typhi	6539	99.99	99.99	99.99
Serratia marcescens	14756	99.97	99.99	99.99
Yeast				
Candida albicans	10231	99.52	99.99	99.99

Test Objective:

The purpose of this test is to determine how rapidly and effectively KIMBERLY-CLARK® Instant Hand Sanitizer kills germs.

Test Method:

Time Kill Study

Test Description:

A 4.5mL aliquot of undiluted KIMBERLY-CLARK® Instant Hand Sanitizer was placed in a sterile glass jar at 25° C. An inoculum of 0.5mL of a broth culture containing approximately 10^8 CFU/mL of the test organism was added to the jar. The contents of the jar were then mixed.

After the appropriate test time, neutralizer was added to the jar to stop the activity of the antiseptic and the contents were stirred for 60 seconds. Serial dilutions were prepared, plated, and incubated. This process was repeated for each of the organisms listed above and for each exposure time of 15 seconds, 30 seconds, and 60 seconds. The percent reduction was determined and is reported above.

Date Test Run: January - March 1999

Independent Laboratory: Hill Top Research, Inc., Miamiville, OH

CONCLUSIONS:

KIMBERLY-CLARK® Instant Hand Sanitizer offers effective and fast-acting antimicrobial action against a broad spectrum of microorganisms, including:

- **Gram negative bacteria**
- **Gram positive bacteria**
- **Foodborne bacterial pathogens**
- **Yeasts**

Antimicrobial Efficacy *in vitro:* Minimum Inhibitory Concentration (MICs)

Gram Positive Bacteria	ATCC#	MIC
Bacillus subtilis	19659	1:4
Micrococcus luteus	7468	1:4
Staphylococcus aureus	29213	1:8
Staphylococcus aureus (MRSA)	33592	1:8
Staphylococcus epidermidis	12228	1:8
Staphylococcus haemolyticus	29970	1:8
Staphylococcus hominis	27844	1:16
Staphylococcus saprophyticus	15305	1:32
Streptococcus pneumoniae	6303	1:32
Streptococcus pyogenes	19615	1:8
Gram Negative Bacteria		
Acinetobacter lwoffii	15309	1:32
Bacteroides fragilis	23745	1:8
E. coli 0157:H7	43895	1:8
E. coli	11229	1:8
E. coli	25922	1:4
Enterobacter aerogenes	13048	1:8
Enterococcus faecalis	29212	1:32
Enterococcus faecalis (MDR)	51299	1:8
Enterococcus faecium	19434	1:8
Haemophilus influenzae	19418	1:16
Klebsiella pneumoniae	10031	1:8
Proteus mirabilis	7002	1:8
Pseudomonas aeruginosa	15442	1:8
Pseudomonas aeruginosa	27853	1:4
Salmonella typhi	6539	1:8
Serratia marcescens	14756	1:32
Yeast		
Candida albicans	10231	<1:4

Test Objective:

The objective of this test is to determine the minimum concentration of the product which will inhibit growth of bacterial or fungal organisms in a laboratory study.

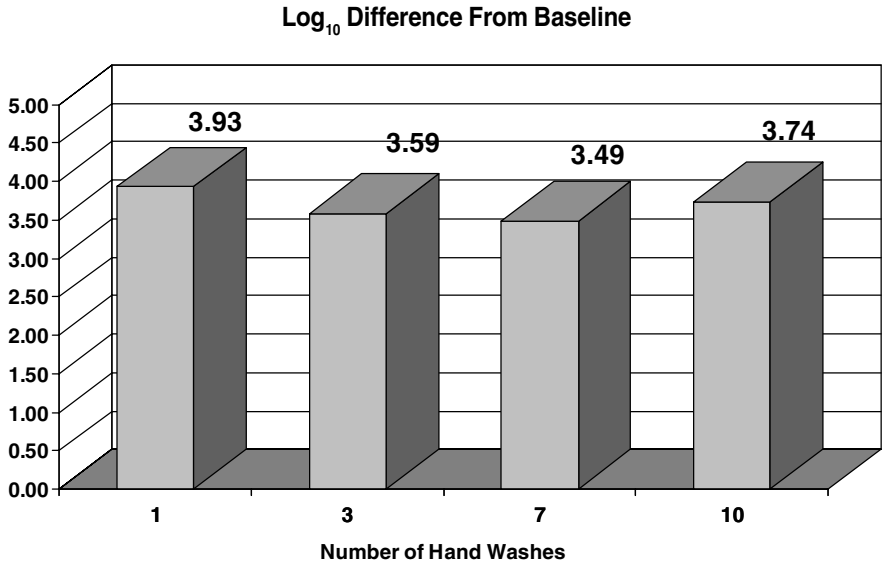
Test Description:

For each organism to be tested, serial dilutions of KIMBERLY-CLARK® Instant Hand Sanitizer were prepared. Each dilution within a series was challenged with approximately 5 x 10^4 colony forming units of the organism. The plates were then incubated. The Minimum Inhibitory Concentration (MIC) reported is the lowest dilution in which growth of the organism is completely inhibited.

Date Test Run: January - March 1999

Independent Laboratory: Hill Top Research, Inc., Miamiville, OH

Antimicrobial Efficacy *in vivo:* Glove Juice Test



Test Objective:
The objective of this study is to determine the ability of the product to reduce transient microbial flora on the skin.

Test Method:
Efficacy Evaluation of Health Care Personnel Hand Wash Products; Glove Juice Test

Test Description:

1) Pre-Test Period
   Subjects refrain from using any antibacterial products for one week prior to the study and wear rubber gloves while doing household chores.
2) Baseline
   Three 1.5mL aliquots of *Serratia marcescens* (minimum of 10^8 organisms per mL) are added to each subject's hands. After each aliquot is added, the suspension is rubbed thoroughly over the surface of both hands for 20 seconds (application and rubbing). Between each aliquot, hands are allowed to air dry.

   Plastic bags with low bioburden are placed on each of the subject's hands. A 75mL aliquot of stripping solution is added to each bag. The bag is secured, and massaged for 1 minute. An aliquot of the fluid is then aseptically obtained to determine the baseline bacterial count. The subject's hands are then washed thoroughly with a non-medicated soap, and dried.
3) Treatment Procedure
   Hands are contaminated with *Serratia marcescens* as in Step 2, paragraph 1. After the hands have been contaminated, they are treated with the test product. Five mL of the product is applied to the subject's hands and rubbed vigorously over hands and lower forearms until dry. A second 2.5mL aliquot is applied and allowed to dry. Particular attention is paid to the nails and interdigital spaces. Water and/or toweling are not used in this process.

   This procedure is repeated 10 times with at least 5 minutes between each treatment. Within 5 minutes of completion of the first, third, seventh, and tenth treatments, hands are sampled as in paragraph 2.

Date Test Run: February 1999

Independent Laboratory: Hill Top Research, Inc., Miamiville, OH

CONCLUSIONS:

- **Kimberly-Clark® Instant Hand Sanitizer demonstrates effective antimicrobial activity on the skin, reducing transient organisms by as much as 99.98%.**
- **Kimberly-Clark® Instant Hand Sanitizer effectively reduces transient microorganisms from the skin following single and multiple uses.**
- **Kimberly-Clark® Instant Hand Sanitizer meets the requirements of the CDC Guidelines for Hand Washing and Hospital Environmental Control (Category III).**

Chlorine Equivalency Testing

Test Objective:

The purpose of this study was to determine germicidal activity of the KIMBERLY-CLARK® Instant Hand Sanitizer compared to 50 ppm available chlorine from sodium hypochlorite.

Test Description:

Solutions of sodium hypochlorite (NaOCl 50 ppm of available Cl^-) were prepared. Ten mL of each solution was brought to a temperature of 20° C in a water bath. Starting with the 50 ppm solution, 0.05mL of the test organism was added. The sample was then mixed and returned to the water bath. After 1 minute, a sample of the solution was removed with a 0.4mm loop and cultured. Thirty seconds after this sample was taken, another 0.05mL sample of the culture was added to the 50 ppm solution. It was mixed, returned to the water bath and a sample removed after 1 minute for culture as above. This was repeated until a total of 10 aliquots of culture were added. All samples removed during the study were incubated for the appropriate time.

The above procedure was repeated with undiluted KIMBERLY-CLARK® Instant Hand Sanitizer replacing the NaOCl solution.

Equivalency is determined by the comparison of the KIMBERLY-CLARK® Instant Hand Sanitizer results to the NaOCl control data. The level of germicidal activity of the KIMBERLY-CLARK® Instant Hand Sanitizer is considered to be equivalent to a particular control solution if the growth is absent in as many consecutive tubes in the series as the control.

The test organisms used in the study were *Staphylococcus aureus* (ATCC 6538) and *Salmonella typhi* (ATCC 6539).

Date Test Run: February 1999

Independent Laboratory: Hill Top Research, Inc., Miamiville, OH

CONCLUSIONS:

The KIMBERLY-CLARK® Instant Hand Sanitizer product is equivalent to >50 ppm of available chlorine.

Skin Irritancy Study: Human Repeat Insult Patch Test

Test Objective:

To determine the potential of KIMBERLY-CLARK® Instant Hand Sanitizer to induce irritation and/or allergic contact sensitization.

Test Method:

Human Repeat Insult Patch Test

Test Description:

203 subjects tested the product using the following procedure:

Approximately 0.2 grams of product was applied to a 3/4" x 3/4" absorbent pad on a clear adhesive dressing (referred to as a "patch"). This patch was then applied to the designated test site on the upper back of the subject.

Induction Phase:
Patches were applied to the same site 3 times per week for a total of 9 applications. Removal of the first patch was supervised and the skin was evaluated using the scale below. The remainder of patches were removed 24 hours after application by the subject. The site was evaluated prior to reapplication of the patch. With the exception of the first reading, a score of 2 on any site resulted in the application of the next patch to an adjacent site. Application was discontinued if a level 2 was seen on this new site, or if a level 3 or 4 was observed. Rest periods of 24 hours followed each Tuesday and Thursday removal and a rest period of 48 hours followed each Saturday removal.

Challenge Phase:
Approximately 2 weeks after the final induction application, a challenge patch was applied to a virgin test site adjacent to the original induction site. The patch was removed and the skin evaluated at 24 hours and 72 hours post-application.

Evaluation Scale:

0 No visible skin reaction
+ Barely perceptible or spotty erythema
1 Mild erythema covering most of the test site
2 Moderate erythema, possible presence of edema
3 Marked erythema, possible edema
4 Severe erythema, possible edema, vesiculation, bullae and/or ulceration

Date Test Run: October-November 1998

Independent Laboratory: Consumer Product Testing Company, Fairfield, NJ

Test Results:

All test scores of 0, indicating that no dermal reactions were observed.

CONCLUSIONS:

KIMBERLY-CLARK® Instant Hand Sanitizer is safe for use on the skin, and does not indicate any potential for dermal irritation or allergic reactions.

Safe For Indirect Food Contact Use

KIMBERLY-CLARK® Instant Hand Sanitizer is considered safe for indirect food contact use based on the demonstrated and recognized human safety of the ingredients. All ingredients are on the FDA GRAS (Generally Recognized As Safe) List.

Latex Glove Compatibility Study

Test Objective:
The purpose of this test was to determine whether KIMBERLY-CLARK® Instant Hand Sanitizer has the potential to damage or degrade latex gloves.

Test Description:
Subjects had KIMBERLY-CLARK® Instant Hand Sanitizer applied to one hand, then wore latex gloves on both hands for one hour.

Glove Testing:
After one hour, the gloves were removed and examined for evidence of damage or compromised integrity.

Date Test Run: January - February 1999

CONCLUSIONS:

KIMBERLY-CLARK® Instant Hand Sanitizer does not damage or degrade latex gloves.

Ingredient List

Active Ingredient:	62% Ethyl Alcohol
Inactive Ingredients:	Purified Water Carbomer Aminomethyl Propanol Glycerin Natural Fragrance Oil

Notes

Notes

Our Guarantee

If, for any reason, our products do not meet your expectations, Kimberly-Clark will reimburse you* for your initial purchase, via FREE product, for up to $1,000.

Just contact your local Kimberly-Clark representative and fill out the Guarantee of Satisfaction form with your initial proof of purchase. We will reimburse you, "No Questions Asked."

We're only a phone call away. For more information, or for the name of the Kimberly-Clark distributor nearest you, call our Customer Solutions Center at 1-888-346-4652 or look for us on the World Wide Web at www.kcprofessional.com.

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