DOES PRODUCT FORMAT IMPACT EFFICACY OF ALCOHOL-BASED HAND HYGIENE PRODUCTS?

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Abstract

Background / Objectives: Hand hygiene is one of the most important interventions for preventing the spread of hospital-associated infections. Alcohol-based hand hygiene products have been recommended by the WHO for use in Healthcare settings. Traditionally these products have been gels, and only recently have foams and wipes been introduced into hospitals. The aim of this study is to determine whether there are differences in the antimicrobial efficacy of alcohol-based hand hygiene products with different formats: gel, foam, and wipe.
Methods: Test products chosen were representative of alcohol-based products currently found in hospital settings including a 70% ethanol gel hand sanitizer, a 70% ethanol foam hand sanitizer, and a 62% ethanol hand sanitizing wipe. These products were tested against various standard test methodologies *in vitro*: EN 1275 versus *Candida albicans*, ASTM E 1052 versus 2009 H1N1 Influenza, and a standard Time-Kill methodology (ASTM E 2315) versus various bacteria of importance in hospitals, including MRSA. Products were also assessed *in vivo* utilizing EN 1500 with application of 3 ml of test product for 30 seconds.
Results: All products achieved greater than 4 log_{10} reduction against all organisms tested *in vitro*. All products met the *in vivo* requirements of EN 1500 and showed equivalent efficacy to the reference product.
Conclusions:
Performance of ≥62% ethanol hand hygiene products was independent of product format.
Alcohol-based hand sanitizing wipes and foam hand sanitizers should be considered as reliable as gel hand sanitizers for the reduction of microorganisms on the hands.

Materials and Methods

Test Products:
Products representative of those found in health care settings in Canada were chosen for this evaluation. These included a 62% ethanol (EtOH) wipe (PURELL® Alcohol Hand Sanitizing Wipes), a 70% EtOH gel (PURELL 70 Instant Hand Sanitizer), and a 70% EtOH foam (PURELL 70 Instant Hand Sanitizer Moisturizing Foam). All products were manufactured by GOJO Industries, Inc., Akron, Ohio.
EN 1275:
Products were tested according to EN norm 1275[1], where an 80% concentration of test product was exposed to *Candida albicans* (ATCC 10231) for 30 seconds.
Virucidal Suspension Test (E 1052):
Products were tested according to ASTM E 1052-06, "Standard Test Method for Efficacy of Antimicrobial Agents Against Viruses in Suspension". The challenge virus was Swine-like H1N1 Influenza a virus strain A/California/04/2009 (CDC ID#2009712047). Test products were mixed with virus suspension to give a 90% concentration of test product. After a 15 seconds exposure, the virus was neutralized by dilution in 1x Minimum Essential Medium. Selected dilutions of the medium/test product mixture were added to cultured host cells (Madin Darby Canis Kidney (MDCK [ATCC#CCL-34]) and incubated at 37°C with 5% CO_2 for a period of 5-14 days. Residual infectious virus was detected by viral-induced cytopathic effect, and a 50% tissue culture infectious dose ($TCID_{50}$) was calculated using the Spearman-Kärber calculation. Log_{10} of infectivity was calculated, and Log_{10} reductions were calculated by comparison to the virus control. Evaluations included a virus control, cytotoxicity control, neutralization control, and negative control.
Time-Kill (E 2315):
Products were tested according to ASTM E 2315, "Standard Guide for Assessment of Antimicrobial Activity Using a Time-Kill Procedure". The test organisms was prepared to reach a challenge suspension of 10^9 CFU/mL. The initial population was determined by ten-fold dilutions in Butterfield's Phosphate Buffer with product neutralizers (BBP++). A 0.1mL aliquot of a challenge suspension containing 10^9 CFU/mL was transferred to sterile test tube containing 9.9mL of test article for a 15 seconds exposure. An aliquot was removed and neutralized and serially diluted in BBP++, and plated in duplicate using TSA+. Plates were incubated at 35°±2°C for 48-72 hours, or until sufficient growth was observed. A neutralization study according to ASTM E 1054-02 was conducted to ensure that the neutralizing solution BBP++ was effective. Following incubation, colonies on plates were counted and the log_{10} reductions were calculated using the following equation:

$$Log_{10}\ Reduction = Log_{10}IP - Log_{10}P_{EX}$$

$Log_{10}IP$ = Initial population of challenge species (CFU/mL); $Log_{10}PEX$ = Average population after exposure to each of the test formulations (CFU/mL)
EN 1500:
Products were tested against *Escherichia coli* K12 NCTC 10538 according to EN 1500[2], where 3 ml of product was applied to the hands for a 30 seconds contact time. Log10 reductions were calculated for each product and comparisons were made to the reference product, 2 applications of 3 ml of 60% isopropanol for a 60 seconds contact time. A total of 12-15 subjects were evaluated for each test product.

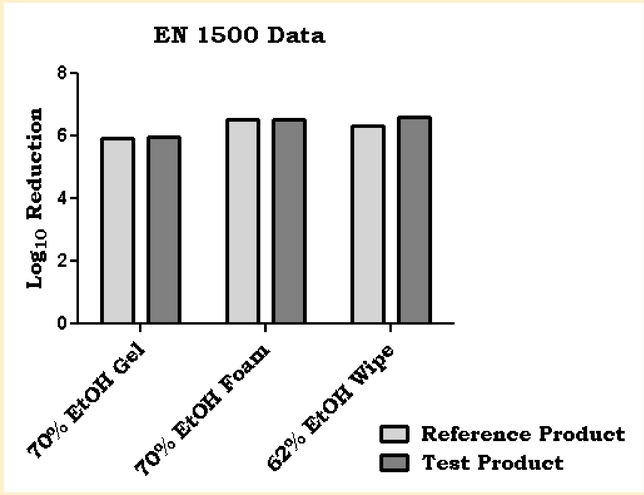
Results

			Log_{10} Reduction		
Method	**Organism**	**ATCC #**	**70% EtOH Gel**	**70% EtOH Foam**	**62% EtOH Wipe**
EN 1275	*Candida albicans*	10231	≥4.04	≥4.54	≥4.54
E 1052	2009 H1N1 Influenza		≥4.25	≥4.25	≥4.25
E 2315	*Acinetobacter baumannii*	19606	≥6.57	≥7.37	≥6.59
E 2315	*Bacteroides fragilis*	29762	≥6.88	≥6.74	≥7.27
E 2315	*Enterococcus faecium* MDR;VRE	51559	≥6.28	5.52	≥6.41
E 2315	*Escherichia coli* (O157:H7)	43888	≥6.15	≥6.30	≥6.06
E 2315	*Haemophilus influenzae MDR*	33930	≥6.30	≥6.42	≥6.53
E 2315	*Klebsiella pneumoniae*	13883	≥6.49	≥6.11	≥6.08
E 2315	*Micrococcus luteus*	7468	≥5.58	≥5.65	≥4.99
E 2315	*Proteus mirablis* ESBL	BAA-856	≥6.28	≥5.94	≥6.12
E 2315	*Pseudomonas aeruginosa*	15442	≥6.29	≥6.20	≥6.06
E 2315	*Serratia marcescens*	14756	≥6.34	≥6.22	≥6.01
E 2315	*Staphylococcus aureus*	6538	≥5.97	≥6.81	≥6.33
E 2315	*Staphylococcus aureus* MRSA	33591	≥6.27	≥7.02	≥6.51
E 2315	*Staphylococcus epidermidis*	12228	≥6.17	≥6.77	≥6.15
E 2315	*Staphylococcus haemolyticus*	43253	≥5.82	≥6.81	≥6.07
E 2315	*Staphylococcus hominis*	27845	≥5.23	≥6.43	≥5.96
E 2315	*Staphylococcus saprophyticus*	49453	≥5.86	≥6.82	≥6.54
E 2315	*Streptococcus pneumoniae*	33400	≥5.53	≥4.77	≥4.15
E 2315	*Streptococcus pyogenes*	19615	≥6.25	≥6.15	≥6.77

•All products achieved >99.99% reduction against all organisms tested using *in vitro* Time-Kill, EN 1275, and Viral Suspension Tests.

•All products met the requirements of EN 1500 as they were all statistically equivalent to the reference product, 60% isopropanol.

•All test products achieved >5 log_{10} reduction *in vivo* using EN 1500, which was consistent with the *in vitro* results where all products achieved >6 log_{10} reduction against *E. coli*.



Conclusions

•Product format did not impact efficacy, as all products showed equivalent efficacy *in vitro* and *in vivo* despite different product formats (gel, foam, and wipe). Therefore, efficacy of foams and wipes should be considered equivalent to gels.

•This data supports US CDC[3], WHO[4], and CHICA-Canada[5] recommendations for use of >60% alcohol-based hand hygiene products, since all products tested ranging from 62-70% ethanol, with various product formats were efficacious.

•In this study, *in vitro* data were a good predictor of the efficacy observed *in vivo* using EN 1500.

•Based upon the Time-Kill and EN 1500 results, all products tested would meet the bactericidal test requirements outlined in Health Canada's Guidance for Human-Use Antiseptic Drugs used in Health-Care settings, as all products achieved >5 log_{10} reduction *in vitro* and >3 log_{10} reduction *in vivo*.

References

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