Broad Spectrum Efficacy of a 70% Ethanol Gel and Foam Hand Rub when Tested According to Health Canada Recommendations

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ABSTRACT

Background/Objectives

In 2009 Health Canada issued a guidance describing efficacy requirements to market an alcohol-based hand rub (ABHR) in healthcare including requirements for reducing bacteria, fungi and viruses on hands (*in vivo*). This guidance raises the bar for efficacy since previously many of these organisms were only tested *in vitro*. The objective of this study was to evaluate two ABHRs for broad spectrum antimicrobial efficacy using *in vivo* efficacy standards recommended by Health Canada.

Methods

A 70% ethanol ABHR gel and foam were evaluated for bactericidal efficacy using ASTM E 1174 and EN 1500 at a dose of 2.0 ml and 3.0 ml for 30 seconds, respectively. Fungicidal efficacy was evaluated using the fingerpad method (ASTM E 2613) for 30 seconds. Virucidal efficacy was evaluated using the whole hand method (ASTM E 2011) with a dose of 3 ml.

Results

The gel and foam reduced *Escherichia coli* by >4 log and *Serratia marcescens* by >3 log, respectively. The gel and foam reduced *Candida albicans* by >3.5 log, and *Aspergillus brasiliensis* by >4 log, respectively. The gel and foam reduced Murine Norovirus by 3.20 and 2.80 log, respectively, and the gel reduced Rotavirus by 4.30 log, Adenovirus by 4.10 log, and Rhinovirus by 3.55 log.

Conclusions

Both ABHR exceeded the minimum Health Canada efficacy requirements for the organisms tested. A well-formulated gel and foam ABHR can be highly efficacious with broad-spectrum antimicrobial activity.

BACKGROUND

In 2009 Health Canada published a guidance that includes efficacy guidelines for alcohol based hand rubs used in Health Care settings[1]. The *in vivo* requirements for bactericidal efficacy are for products to achieve a minimum 3 $\log_{10}$ reduction at the lower limit of the 95% confidence interval. For *in vivo* fungicidal and virucidal efficacy products must achieve a minimum 2 $\log_{10}$ reduction at the lower limit of the 95% confidence interval. The Health Canada requirement to demonstrate virucidal activity includes testing against Hepatitis A virus (HAV), however products were not tested against HAV in this study.

1. Health Canada Guidance Document Human-Use Antiseptic Drugs, November 2009.

METHODS

Test Products

PURELL® Advanced Hand Rub (70% ethanol gel) and PURELL Advanced Foam Hand Rub (70% ethanol foam) manufactured by GOJO Industries, Inc., were evaluated with the following methods.

ASTM E 1174 (Health Care Personnel Hand Wash)

Hands were contaminated with *Serratia marcescens* ATCC E14476. The test product was applied to the hands with a volume of 2 ml, and rubbed in until dry. A minimum of 24 subjects were evaluated for each test product for a series of 10 applications, with samples collected after applications 1 and 10. Log_{10} reductions from baseline were calculated.

European Norm (EN)1500

Hands were contaminated with *Escherichia coli* K12 NCTC 10538. 3 ml of test product was applied to the hands for 30 seconds. For the reference, two applications of 3 ml of 60% isopropanol were applied for 30 seconds each. Log_{10} reductions (LRs) of the test product and reference were calculated and statistically compared. The test product must be non-inferior to the reference.

ASTM E 2613-08

Fingerpads of 10 participants were contaminated with culture of the fungi to be tested. The test product was exposed to contaminated fingerpads for 30 seconds prior to sampling. Log_{10} reductions from baseline were calculated.

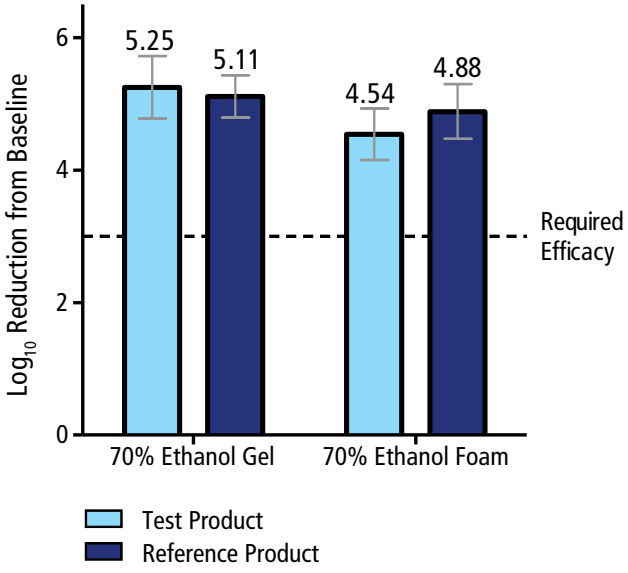
ASTM E 2011-09

Hands of 5 participants were contaminated with the test virus. 3 ml of test product was applied to the hands and rubbed in until dry. Log_{10} reductions from baseline were calculated.

RESULTS

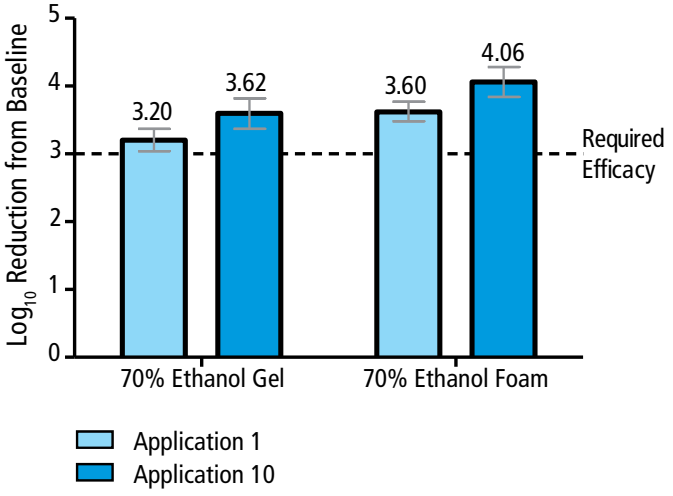
In vivo Bactericidal Data

Figure 1: EN 1500 – Hygienic Hand Rub



Test products were not statistically inferior to reference.

Figure 2: ASTM E 1174 – Health Care Personnel Handwash



RESULTS

Figure 3: *In vivo* Fungicidal Data – ASTM E 2613

Test Products	Test Organism	Bioresource	Mean Log_{10} Reduction	95% Confidence Interval
70% Ethanol Gel	*Candida albicans*	ATCC #10231	3.56	3.24 – 3.88
	Aspergillus brasiliensis	ATCC # 16404	4.34	4.25 – 4.44
70% Ethanol Foam	*Candida albicans*	ATCC # 10231	3.51	3.34 – 3.68
	Aspergillus brasiliensis	ATCC # 16404	4.22	3.92 – 4.52

Figure 4: *In vivo* Virucidal Data – ASTM E 2011

Test Products	Test Organism	Bioresource	Mean Log_{10} Reduction	95% Confidence Interval
70% Ethanol Gel	Rotavirus	ATCC #VR-2018	4.30	4.04 – 4.56
	Rhinovirus	ATCC #VR-284	3.55	3.15 3.96
	Adenovirus	ATCC #VR-1516	4.10	3.58 – 4.62
	Murine Norovirus	FLI Virusbank #RB-651	3.20	3.06 – 3.34
70% Ethanol Foam	Murine Norovirus	FLI Virusbank #RB-651	2.80	2.46 – 3.14

SUMMARY & CONCLUSIONS

- **Both 70% ethanol ABHRs met EN 1500 efficacy requirements in a single use by achieving a log_{10} reduction of bacteria that was non-inferior to the Reference Product (2 x 3 mL of 60% isopropanol).**
- **The 70% ethanol ABHRs met Health Canada's *in vivo* bactericidal efficacy standards using both EN 1500 (single use) and ASTM E 1174 (single use and ten consecutive uses) by achieving a >3 log_{10} reduction at the lower limit of the 95% confidence interval.**
  - **This indicates products are effective, both immediately after use and after repeated use, that is representative of a clinical healthcare setting.**
- **The 70% ethanol gel and foam also meet Health Canada's standards by achieving greater than 2 log_{10} reduction at the lower limit of the 95% confidence interval for the fungi and viruses tested in this study.**
- **Well-formulated ABHRs can have significant broad spectrum activity when evaluated on hands against bacteria, fungi and viruses.**

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