Hand Rub Formulation: A Critical Component for Meeting Health Canada Healthcare Personnel Handwash Efficacy Standards

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ABSTRACT

Background / Objectives

Alcohol based hand rubs (ABHR) are the primary form of hand hygiene in healthcare settings, and are recommended for preventing the spread of infection. The objective of this study was to compare the efficacy of commercially available ABHR, and determine whether each meets Health Canada efficacy requirements for ASTM E 1174.

Methods

Eight commercially available alcohol-based hand rubs (gels and foams) containing between 62-72% (v/v) ethanol were evaluated using the Healthcare Personnel Handwash (ASTM E1174-94) method with *Serratia marcescens* at 2-ml application volumes. Log_{10} reductions from baseline were calculated after a single use and after 10 consecutive uses. Test product efficacy was compared using a two-factor analysis of variance (α=0.05).

Results

Only products with ≥70% ethanol achieved a 3 log_{10} reduction after 1 application. However, only 2 test products, a well-formulated 70% ethanol gel and a well-formulated 70% ethanol foam, produced a 3-log_{10} reduction following the tenth application, and were therefore the only products to meet Health Canada efficacy requirements for ASTM E1174 at a 2 ml dose. Additionally, these 2 test products were statistically superior to all other test products after 10 applications ($P<0.05$).

Conclusions

Product formulation was found to have a greater influence on efficacy than alcohol concentration, as products with identical or lesser amounts of active ingredient had superior efficacy. These results demonstrate that simply having an alcohol concentration of 70% is not sufficient to meet Health Canada efficacy standards for ASTM E1174 at a 2 ml dose.

METHODS

There are two *in vivo* methods for assessing in vivo bactericidal efficacy in health care settings: EN 1500 and ASTM E1174. The ASTM E1174 method was chosen as a more representative assessment of clinical practice as it evaluates products after both a single use and repeated use. Health Care Personnel Hand Wash (HCPHW) studies were conducted according to the ASTM E 1174-94 "Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations". A total of 8 test products were evaluated as shown in Table 1. A neutralization study per ASTM E1054-08 was successfully performed to ensure the neutralizer employed in this study was effective. Subjects hands were contaminated with *S. marcescens* (ATCC #14756). The test product was applied to the hands with a volume of 2 ml, and rubbed in until dry. A minimum of 12 subjects were evaluated for each test product for a series of 10 applications, with samples completed after applications 1 and 10. Log_{10} reductions from baseline were calculated and statistical analysis was conducted utilizing an ANOVA (α=0.05). For demonstration of bactericidal efficacy when products are tested according to ASTM E1174, Health Canada requires a minimum 3 log_{10} reduction[1].

Table 1. Test Products

Product Code	Active Ingredient	Product Name
Gel A*	70% ethanol	PURELL® Advanced Instant Hand Sanitizer
Gel B	70% ethanol	Sween® Isagel® Ethyl Alcohol Gel
Gel C	70% ethanol	Ecolab® Sanigizer® (similar to Ecolab Quik-Care™ Gel)
Gel D	62% ethanol	Ecolab Endure® 320 Advanced Care Waterless Antimicrobial Hand Rinse with Moisturizer
Foam A*	70% ethanol	PURELL Advanced Instant Hand Sanitizer Foam
Foam B	72% ethanol	Deb® InstantFOAM® Alcohol Hand Sanitizer
Foam C	70% ethanol	3M™ Avagard™ Foam
Foam D	62.5% ethanol	Ecolab Quik-Care Waterless Antimicrobial Foaming Hand Rub

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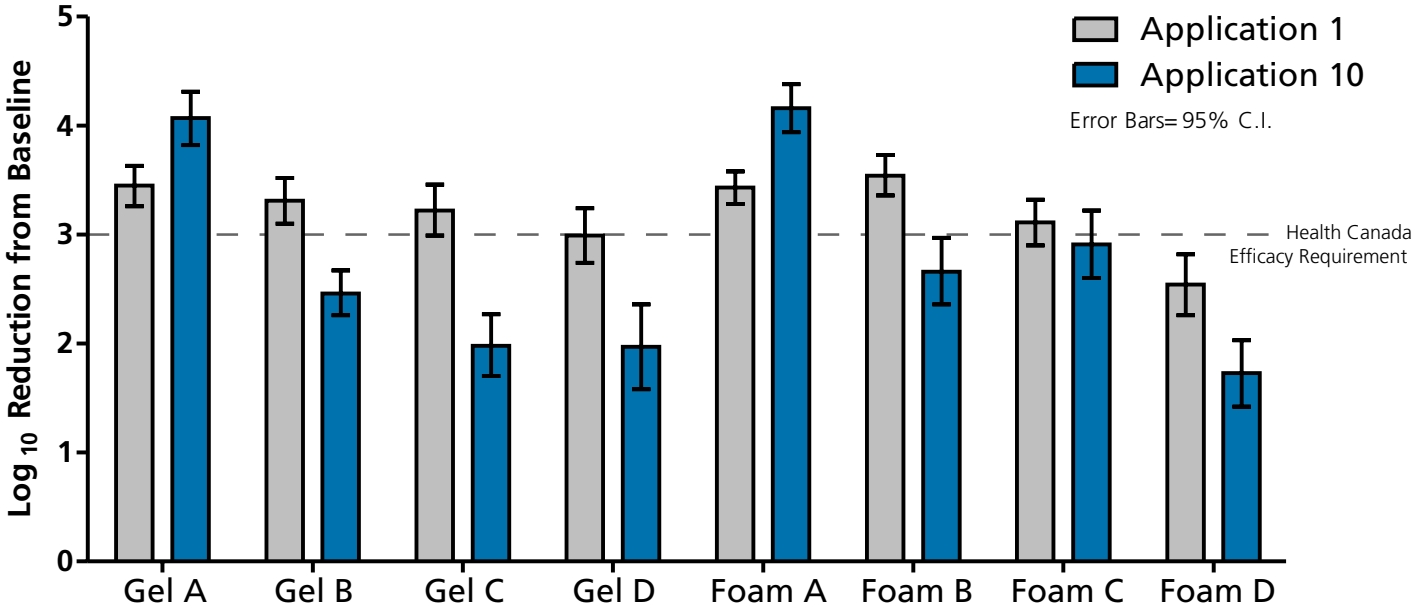
*Data from 2 separate studies was combined

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

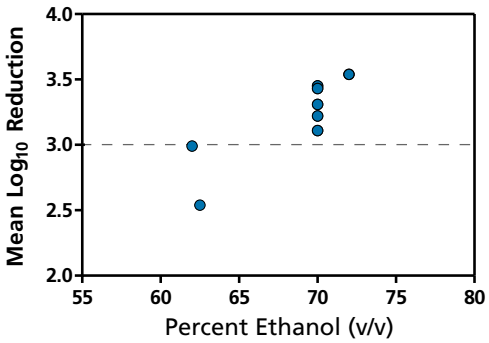
RESULTS

Comparison of ABHR using ASTM E 1174 at a 2 ml Dose

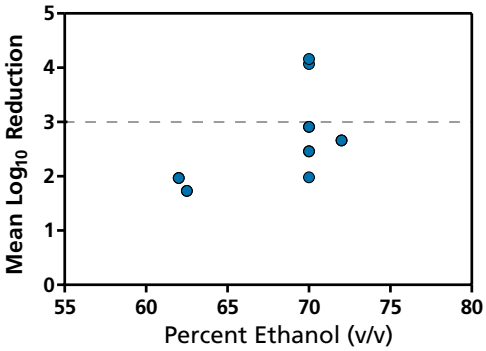


After a single use, Gel A was statistically superior to Foam C; and Gel A and Foam A were superior to Foam D ($P<0.05$). After ten consecutive uses, Gel A and Foam A were statistically superior to all other test products ($P<0.05$).

Comparison of Efficacy vs. Ethanol Level After a Single Use



Comparison of Efficacy vs. Ethanol Level After Ten Repeated Uses



CONCLUSIONS

- **Only 2 products, Gel A and Foam A, met requirements for a minimum 3 log reduction when tested using ASTM E1174 at a reasonable dose of 2 ml at applications 1 and 10. Other products may meet bactericidal efficacy requirements if tested at a greater dose.**
- **The efficacy of some products declines with repeated use. Therefore, obtaining efficacy data on repeated uses may be clinically important.**
- **Product efficacy varied greatly despite similar ethanol concentrations; thus highlighting the importance of total product formulation, and showing that simply including an active ingredient (e.g. 70% ethanol) does not guarantee product efficacy.**
- **Product format (foam or gel) did not have an impact on efficacy as 2 products with similar formulations, Gel A and Foam A, had equivalent *in vivo* product performance.**
- **This data was collected using the E1174 test method. Products may meet bactericidal efficacy standards using a different test method.**

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