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 ($\alpha=0.05$).

Table 1. Test Products

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

*Sween and Isagel are trademarks of Coloplast Corp. Ecolab, Sanigizer, Quik-Care, and Endure are trademarks of Ecolab. Deb and InstantFOAM are trademarks of Deb Group Ltd. 3M and Avagard are trademarks of 3M.

*Data from 2 separate studies was combined


Results
Only products with $\geq$70% ethanol achieved a 3 log$_{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.
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).

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.