

Can a General Use Hygienic Hand Rub Kill Human Norovirus, Meet EN Efficacy Norms and Still Be Skin Friendly? Antimicrobial Efficacy and Skin Performance of a Novel Hygienic Hand Rub.

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Presented at the Annual Infection Prevention Society (IPS) Conference
“Infection Prevention 2008” – “Inform, Promote, and Sustain”
September 22-24, 2008, Harrogate, North Yorkshire, UK



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ABSTRACT

Background: Traditionally, hygienic hand rubs that meet EN14476 have high alcohol content and are perceived as damaging to skin. Since they are intended for viral outbreaks, efficacy has taken precedent over skin performance.

Hypothesis: It is possible to meet current infection control community needs and develop an antiviral hygienic hand rub, which is aesthetically pleasing and has proven skin performance when used frequently.

Data Collection Methods: Antimicrobial efficacy: EN 14476, EN 1040, p/EN 13727, EN 14348, EN 1275, EN 1040, EN 12791, ASTM E2315-03 and ASTM E1838-02. Skin care: 21-Day Cumulative Irritation and Exaggerated Handwash.

Data Analysis Methods: Data were analyzed according to EN norm requirements or using the appropriate parametric statistics (alpha = 0.05, SPSS v13.0, Chicago, USA).

Results: PURELL® VF481 demonstrated complete inactivation (>4log₁₀ reduction) of Poliovirus and Adenovirus using EN14476. Testing against Human Norovirus by Fingepad (ASTM E1838-02) produced a >3log₁₀ reduction. Virucidal suspension tests against SARS-CoV, Avian Influenza H5N1, Human Influenza A and B, HIV-1, Hepatitis A, B & C, RSV, and human Rotavirus demonstrated quick, high level, broad spectrum virucidal efficacy. Bactericidal 15-second suspension findings illustrate complete reduction (>5log₁₀). In-vivo dermatologic evaluations reveal excellent skin performance after repeated, frequent use (Measurements: erythema, moisture, and transepidermal water loss). The cumulative irritation score is very mild (0.07, 0-4 scale). Benchmarking data are positive.

Conclusion: A new general use hygienic hand rub, PURELL® VF481, is the first EN14476 compliant product with proven Human Norovirus efficacy and robust skin performance. It should be strongly considered for improved infection control in Europe.

INTRODUCTION

Currently, there are very few products that meet the virucidal efficacy norm EN 14476, since the high success criteria and worst case test conditions (dilution to 80%) ensure that only truly broad spectrum, high efficacy virucidal products pass the requirements. Those products that do meet the EN 14476 norm are typically comprised of high alcohol (>80%) or blends of active ingredients, which can be unacceptable for end users because they are irritating to skin and / or are aesthetically unappealing. Although efficacy takes precedence over skin performance for these products, to promote compliance, hygienic hand rubs must be skin friendly even when used with high frequency.

METHODS

Exaggerated Hand Wash: To replicate the dry, damaged skin of health care workers, 22 healthy female subjects underwent a 7 day wash out period where Ivory® bar soap was applied for 9 consecutive washes per day and used exclusively for hand washing throughout the wash out period. During the test period, 2ml of hygienic hand rub was applied 25 times daily (1ml applied to each side of the hand, rubbed in by a technician for 30 seconds, air dried for 40 seconds), in approximately a 1 hour period total, for 4 consecutive days to emulate the high frequency use conditions of a healthcare setting. Each day, baseline and post-wash corneometer (skin hydration) measurements, transepidermal water loss (skin barrier integrity) measurements, clinical grading of erythema, clinical grading of dryness, and subject self-assessment of dryness, redness, tightness, and overall skin condition were captured.

Human Norovirus Virucidal Fingepad Assays: Fingepad assays were conducted according to ASTM E 1838-02. Participants washed, disinfected and dried their hands and then, ten µl of a 20% stool suspension containing Norwalk virus were inoculated onto the fingerpads of both hands. Virus was immediately eluted from one fingerpad in order to measure the input concentration of virus. After drying for 20 minutes, virus from another finger was eluted to measure the remaining amount of virus after drying. The dried virus on the remaining fingerpads were then exposed to 1 ml of test article for 30 seconds. Any remaining virus was then eluted off the fingerpads. Norwalk virus in the eluates was measured by quantitative real-time RT-PCR using Norwalk virus-specific primers and probes. Log₁₀ reductions of virus were calculated to examine the efficacy of VF481 against Norwalk virus.

EN Norm and other Standard Methods: EN 14476, EN 1500, EN 12791, EN 1275, p/EN 13727, EN 1050, EN 14348, and ASTM E 1052-96 for supplemental viruses were conducted and analyzed according to the published standards

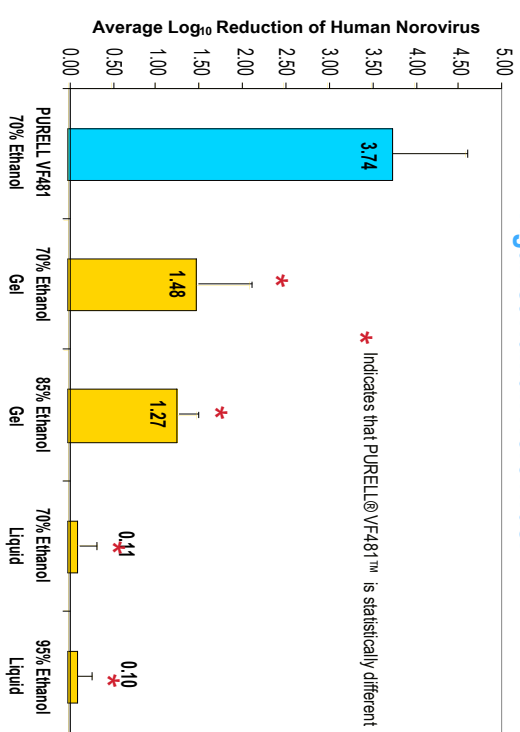
RESULTS

Standard Efficacy Method Test Results:

Method	Purpose	Result
EN 14476*	Virucidal	Adenovirus Type 5: > 4 log ₁₀ reduction in 60 seconds Poliovirus Type 1 (Sabin): > 4 log ₁₀ reduction in 90 seconds
ASTM E 1052-96*	Virucidal	Inactivation below the detection limit in 15 seconds against SARS-CoV, Rotavirus, HIV-1, Herpes Simplex, Respiratory Syncytial virus, Influenza A, Influenza A H5N1, Hepatitis A, DHBV & BVDV (Hepatitis B & C surrogates), Mumps Norovirus
EN 1500	Hygienic Hand Rub	Pass - 3ml dose, 30 second application
EN 12791	Surgical Rub	Pass - 3ml dose, 60 second application
EN 1040	Bactericidal	Pass
p/EN 13727	Bactericidal	Pass
EN 1275	Yeasticidal & Fungicidal	Pass
EN 14348	Tuberculocidal	Pass

*Complete results shown in 2007 IFIC Conference poster

Activity of Various Hygienic Handrubs Against Human Norovirus:



Human Norovirus Virucidal Fingepad Results:

PURELL® VF481™ reduced Norwalk virus by greater than 99.9% or 3 log₁₀ after a 15-second contact. In addition, PURELL® VF481™ was statistically greater than four commercial ethanol based hygienic hand rubs, including some making EN 14476 efficacy claims. These data suggest that virucidal activity against poliovirus and ad enovirus, as evidenced by passing EN 14476, may not be sufficient to predict activity against other non-enveloped viruses such as human norovirus. Therefore, all viral efficacy data should be carefully considered when human norovirus prevention is critical.

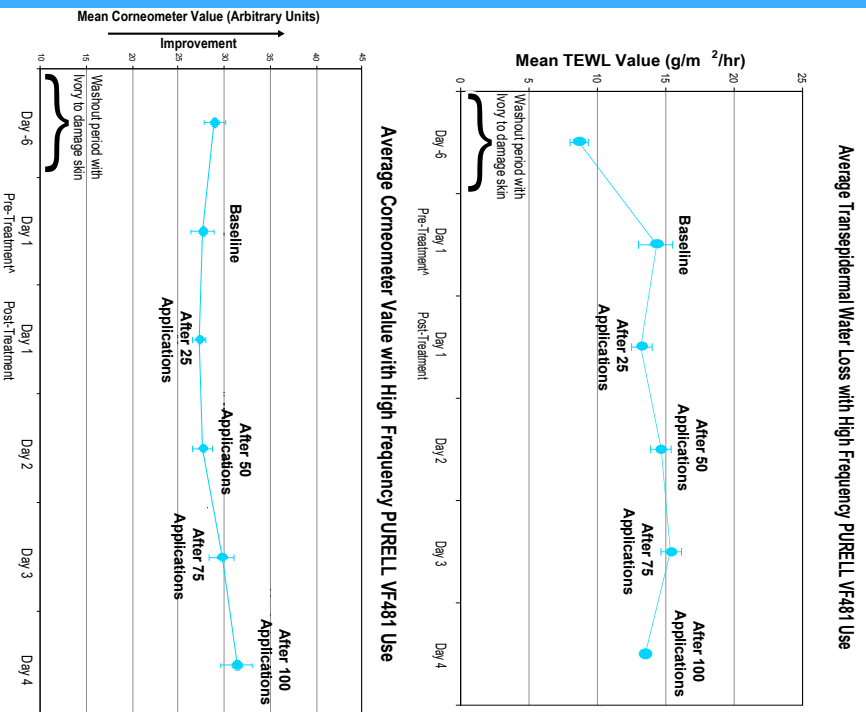
Exaggerated Hand Wash Skin Care Performance Results:

TEWL and Corneometer results demonstrate there are no statistically significant effects of PURELL® VF481™ on skin moisture levels or skin barrier integrity. Therefore, the product maintains skin condition even with high frequency use.

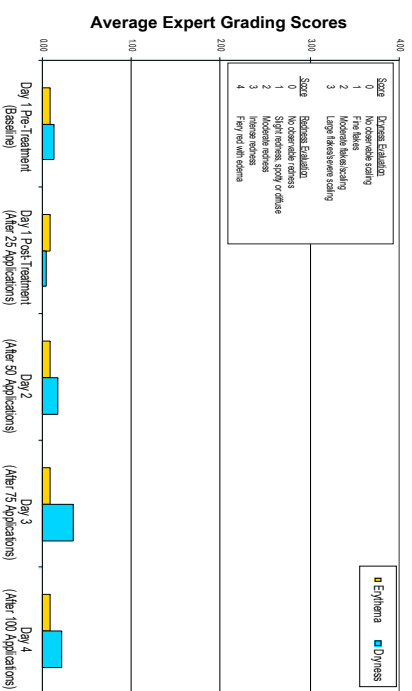
Visual grading of erythema and dryness as determined by an expert grader show no statistically significant increase over the course of the study. The average erythema and dryness scores for most subjects were 0 (no observable redness or scaling). Therefore, objective visual grading suggests that high frequency use of PURELL® VF481™ does not result in visually perceptible damage to the skin.

Subject self assessments of erythema, dryness, tightness and overall skin condition were collected. While individual attributes were on occasion rated moderate (data not shown), the overall rating of skin condition shows acceptable skin performance with a directional improvement in rating from a mean rating of 5.4 to 6.0 (p-value = 0.077).

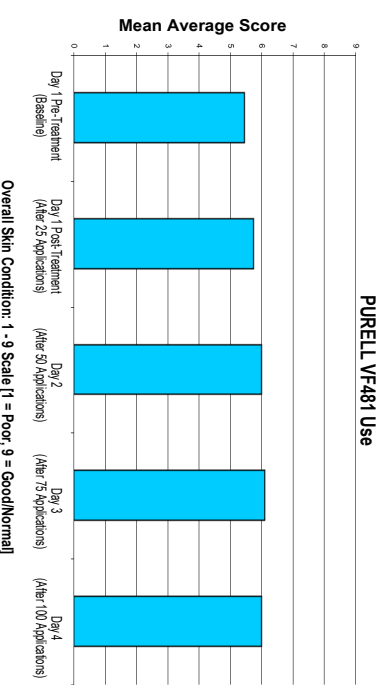
Overall these results show that PURELL® VF481™ maintains skin condition even with high frequency use, therefore it is an acceptable and appropriate skin care solution for healthcare and other professional environments.



Expert Grading of Erythema and Dryness with High Frequency PURELL VF481 Use



Subject Self Assessment of Overall Skin Condition with High Frequency PURELL VF481 Use



CONCLUSIONS

A new general use hygienic hand rub, PURELL® VF481™, is the first EN 14476 compliant product with demonstrated Human Norovirus efficacy and robust skin performance. Therefore, in settings where hygienic hand rub is used with high frequency (e.g. Healthcare) and/or where there is an interest in mitigating Norovirus risk, PURELL® VF481™ should be strongly considered for improved infection prevention and control.

