Technical Information Bulletin

3M™ Avagard™ D Instant Hand Antiseptic for Healthcare Personnel Use

Introduction

Destroys bacteria. Not your skin.

Contains 61% (w/w) ethyl alcohol in an emollient-rich lotion base.

- Kills bacteria without water*
- Advanced liquid crystalline moisturizing formulation
- Helps to prevent dryness and maintain skin integrity

Indications for Use

Avagard D instant hand antiseptic kills 99% of harmful bacteria in 15 seconds without soap and water.* It provides rapid, broad-spectrum bacterial kill while helping to maintain the skin's natural barrier function.

Use instead of handwashing when soap and water are not readily available or convenient, or between handwashings to kill bacteria.

Meet recommendations of APIC[1] and CDC[2] Guidelines for Hand Washing/Hand Antisepsis.

Active Ingredient

- Ethyl Alcohol, 61% (w/w)

Contains no fragrance or perfumes.

* Based on *in vitro* testing against specific bacterial strains.

3M *Innovation*

3M™ Avagard™ D Instant Hand Antiseptic for Healthcare Personnel Use

In Vitro Antimicrobial Efficacy

Objective

The objective of this test was to assess how rapidly Avagard D instant hand antiseptic (61% w/w ethyl alcohol) kills bacteria.

Method

Avagard D instant hand antiseptic was brought in contact with a known population of organisms for a specified period of time at a specified temperature. The activity of the Avagard D instant hand antiseptic was stopped at specified sampling intervals and samples were plated to enumerate the surviving bacteria. The percent reduction from the initial population was calculated for each organism.

Conclusion

Avagard D instant hand antiseptic offers fast and effective reduction of a broad spectrum of microorganisms.

Percent Microbial Kill at 15 and 30 Seconds

ORGANISM	15 SEC.	30 SEC.
Staphylococcus aureus, ATCC 6538	99.1	>99.9
Staphylococcus epidermidis, ATCC 12228	>99.9	>99.9
Staphylococcus aureus (MRSA), ATCC 33592	99.8	>99.9
Klebsiella pneumoniae, ATCC 1031	>99.9	>99.9
Pseudomonas aeruginosa, ATCC 9027	>99.9	>99.9
Burkholderia cepacia, ATCC 25416	>99.9	>99.9
Escherichia coli, ATCC 11229	>99.9	>99.9
Streptococcus pneumoniae, ATCC 6303	>99.9	>99.9
Streptococcus pyogenes, ATCC 19615	98.0	>99.9
Serratia marcescens, ATCC 14756	>99.9	>99.9
Enterococcus faecalis (VRE), ATCC 51299	>99.9	>99.9

In Vivo Antimicrobial Efficacy

Two studies evaluated the antimicrobial effectiveness of 3M™ Avagard™ D Instant Hand Antiseptic compared to control materials in reducing transient bacteria applied to the hands of healthy volunteers. The procedure used in each study was a modified version of the American Society for Testing and Materials (ASTM) E1174-94, Standard Test Method for Evaluation of Healthcare Personnel Handwash Formulations.

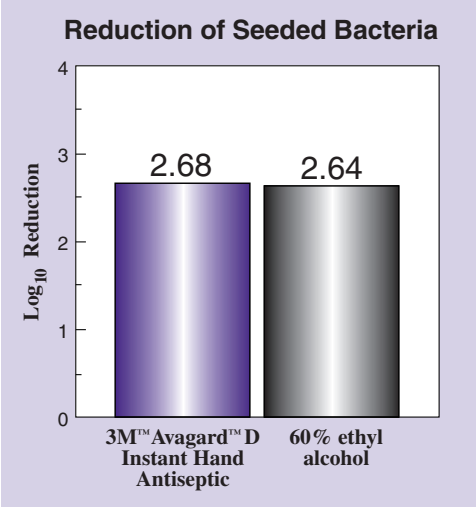
Single-Wash Healthcare Personnel Handwash Study #1

Objective

To evaluate the antimicrobial effectiveness of Avagard D instant hand antiseptic compared to 60% v/v alcohol in reducing transient bacteria, as specified in the Tentative Final Monograph for Health-Care Antiseptic Drug Products (TFM)[3].

Method

This was a single blinded parallel comparison. The hands of thirty-two (32) healthy volunteers were contaminated with *Serratia marcescens* and the baseline level of marker organisms on each volunteer's hands was determined. Following a single handwash, using either Avagard D instant hand antiseptic or 60% alcohol, the glove juice technique was used to recover the surviving bacteria. Log reductions from baseline were calculated for each product.



Conclusion

After one 3 ml application, Avagard D instant hand antiseptic resulted in a 2.68 log reduction (99.8%) of bacteria on contaminated hands, with no significant difference from 60% ethyl alcohol (p=0.91).

Single-Wash Healthcare Personnel Handwash Study #2

Objective

The objective of this study was to evaluate the antimicrobial efficacy of Avagard D instant hand antiseptic compared to Purell® Instant Hand Sanitizer (a leave-on alcohol product, containing 61% ethyl alcohol) and Bacti-Stat® Healthcare Personnel Hand Wash (a wash-off soap, containing 0.3% Triclosan as an active ingredient) in producing an immediate reduction in transient bacteria on the hands, as specified in the Tentative Final Monograph for Health-Care Antiseptic Drug Products (TFM)[3].

Method

This was a single blinded parallel comparison. The hands of fifty-one (51) healthy volunteers were contaminated with *Serratia marcescen*s and the baseline level of marker organisms on each volunteer's hands was determined. Following a single handwash, using either Avagard D instant hand antiseptic, Purell instant hand sanitizer, or Bacti-Stat healthcare personnel hand wash, the glove juice technique was used to recover the surviving bacteria. Log reductions from baseline were calculated for each product.

Conclusion

After one 3 ml application, Avagard D instant hand antiseptic resulted in a 3.01 log reduction of bacteria on contaminated hands. When tested at equal volumes, Avagard D instant hand antiseptic showed no significant difference from Purell instant hand sanitizer (3.15 log reduction). However against Bacti-Stat healthcare personnel hand wash (2.36 log reduction), Avagard D instant hand antiseptic demonstrated better immediate reduction of seeded bacteria.

As set forth in the TFM[3], Avagard D instant hand antiseptic satisfies the acceptance criterion of a 2 log bacterial reduction following a single wash with a healthcare personnel handwash.

Objective

The objective of this study was to compare the relative gentleness of 3M™ Avagard™ D Instant Hand Antiseptic with Purell® Instant Hand Sanitizer with Moisturizers. The effect of frequent exposure to water was also evaluated.

Method

This was a single blinded bilateral comparison. All subjects had Avagard D instant hand antiseptic applied to one hand randomized according to dominance. The other hand was treated with either Purell instant hand sanitizer or a water rinse.

Twelve (12) applications were completed per day, for five (5) days, following label directions on each product. Skin condition was assessed using an expert grader evaluation of skin dryness (Visual Scoring of Skin [VSS] Fig. 1); erythema, and roughness; a subject self-assessment questionnaire (Hand Skin Assessment [HSA] Fig. 2); and an electrical conductance meter measurement of skin surface hydration.

Results

Of forty (40) subjects, twelve (12) discontinued due to dryness, erythema, or discomfort (1-Avagard D instant hand antiseptic, 5-Purell instant hand sanitizer and 6-water). Dryness scores progressively increased after additional applications of Purell instant hand sanitizer and water but not after additional applications of Avagard D instant hand antiseptic. The last expert grader evaluation each study day showed Avagard D instant hand antiseptic was significantly ($p<0.005$) less drying than either Purell instant hand sanitizer or water. Similarly, ratings of erythema and tactile roughness showed Purell instant hand sanitizer was significantly more irritating than Avagard D instant hand antiseptic. Subject self-assessments at days 4 and 5 rated Avagard D instant hand antiseptic significantly ($p<0.02$) better than both Purell instant hand sanitizer and water for skin appearance, intactness, moisture, and sensation. Electrical conductance measurements

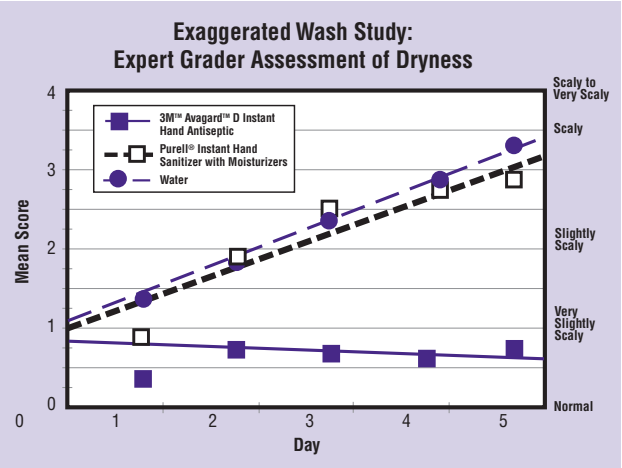


Figure 1

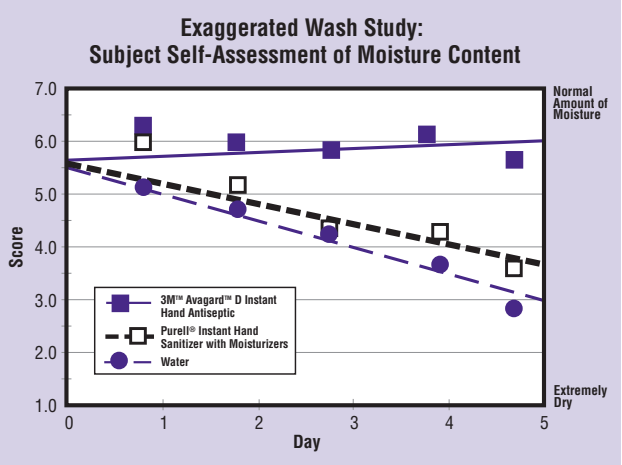


Figure 2

demonstrated that Purell instant hand sanitizer or water reduced skin surface hydration while Avagard D instant hand antiseptic increased skin hydration.

In conclusion, Avagard D instant hand antiseptic was shown to moisturize and help prevent dry cracked skin. It also helped prevent erythema and tactile roughness (compared to the control materials), which are factors in skin damage.

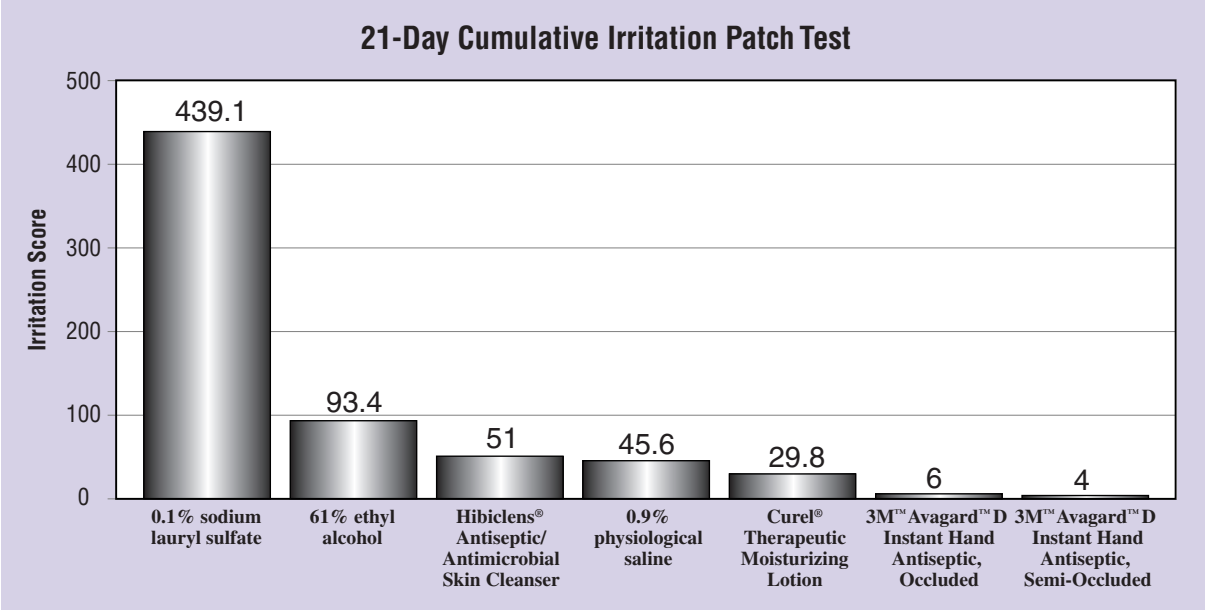
Human Cumulative Irritation Patch Test

Objective

The objective of this study was to determine the relative skin irritation potential of 3M™ Avagard™ D Instant Hand Antiseptic (under occlusion and semi-occluded conditions) and compare these potentials with those of a variety of comparison materials.

Method

The test articles were applied to the upper back of thirty-six (36) healthy volunteers daily for twenty-one (21) days, and remained in contact with the skin for twenty-four (24) hours with each application. Dermal irritation was evaluated daily.



Results

Avagard D instant hand antiseptic was classified as a mild material, under occlusive and semi-occlusive conditions. The irritation scores were significantly less than the control articles of 0.1% sodium lauryl sulfate (positive control), 61% ethyl alcohol, Hibiclens® Antiseptic/Antimicrobial Skin Cleanser, 0.9% physiological saline (negative control), but not significantly different from Curel® Therapeutic Moisturizing Lotion.

Human Repeat Insult Patch Test

Objective

The objective of this study was to determine the potential for inducing sensitization with 3M™ Avagard™ D Instant Hand Antiseptic.

Method

The test article was applied to the upper back of 217 healthy volunteers. The study design consisted of three (3) phases:

- Induction Phase — Nine (9) applications of the test article over a three (3) week period. Patches were worn for forty-eight (48) hours (Monday and Wednesday applications) or seventy-two (72) hours (Friday application) with patch removal/application performed by study staff.
- Rest Period — Two (2) week period between induction and challenge.
- Challenge Phase — Application of the test article to a naive site, scored forty-eight (48) and ninety-six (96) hours post application for reactions indicative of contact sensitization.

Results

There was no evidence suggesting that Avagard D instant hand antiseptic has a potential for contact sensitization.

Latex Glove Compatibility Study

Objective

To determine if Avagard D instant hand antiseptic has a negative effect on the tensile strength and elongation at break of latex medical exam gloves.

Method

Forty-eight (48) dogbone shapes were cut from the palms of the gloves. Each sample was checked for flaws; flawed samples were discarded. Twelve (12) samples were tested as a control without any product on them. Twelve (12) samples were put in contact with Avagard D instant hand antiseptic, and twelve (12) samples were put in contact with mineral oil. A commercially available mineral oil was used as a positive control because of the known effect of mineral oil on latex. Mineral oil is known to swell latex and decrease the tensile strength.

After having contact for ninety (90) minutes, any excess Avagard D instant hand antiseptic or oil was wiped off and glove samples were allowed to stand for another thirty (30) minutes. Within the next thirty (30) minutes, tensile strength and elongation at break were measured.

Results

Avagard D instant hand antiseptic did not significantly affect the tensile strength or the elongation at break of the exam gloves. The treated and untreated control gloves were equivalent in strength and elongation (within 20% with 95% confidence). In contrast, tensile strength and elongation at break were significantly reduced in glove samples treated with mineral oil.

[1] APIC Guideline for Handwashing and Hand Antisepsis in Health Care Settings, 1995 Larson, E.L.

[2] CDC Guideline for Handwashing and Hospital Environmental Control, 1985, Julia S. Garner; Martin S. Favero, Hospital Infections Program Center for Infectious Diseases, Centers for Disease Control and Prevention.

[3] Federal Register Part III, Tentative Final Monograph for Health-Care Antiseptic Drug Products; Proposed Rule. Vol. 59, No 116, (Friday June 17, 1994). Code of Federal Regulations; Title 21 CFR Parts 333 and 369.

3M

Health Care
3M Center, Building 275-4W-02
St. Paul, MN 55144-1000
USA
1 800 228-3957
healthcare@3M.com
www.3M.com/healthcare

3M Canada Inc.
Post Office Box 5757
London, Ontario N6A 4T1
Canada
1 800 563-2921

40% Pre-consumer waste paper
10% Post-consumer waste paper

Curel is a registered trademark of The Andrew Jergens Co.
Purell is a registered trademark of GoJo Inc.
Hibiclens is a registered trademark of AstraZeneca PLC.
Bacti-Stat is a registered trademark of Ecolab.

H.I. 4509
Printed in U.S.A.

Copyright © 3M (IPC) 2000.
All rights reserved.

70-2009-3003-3 WG