

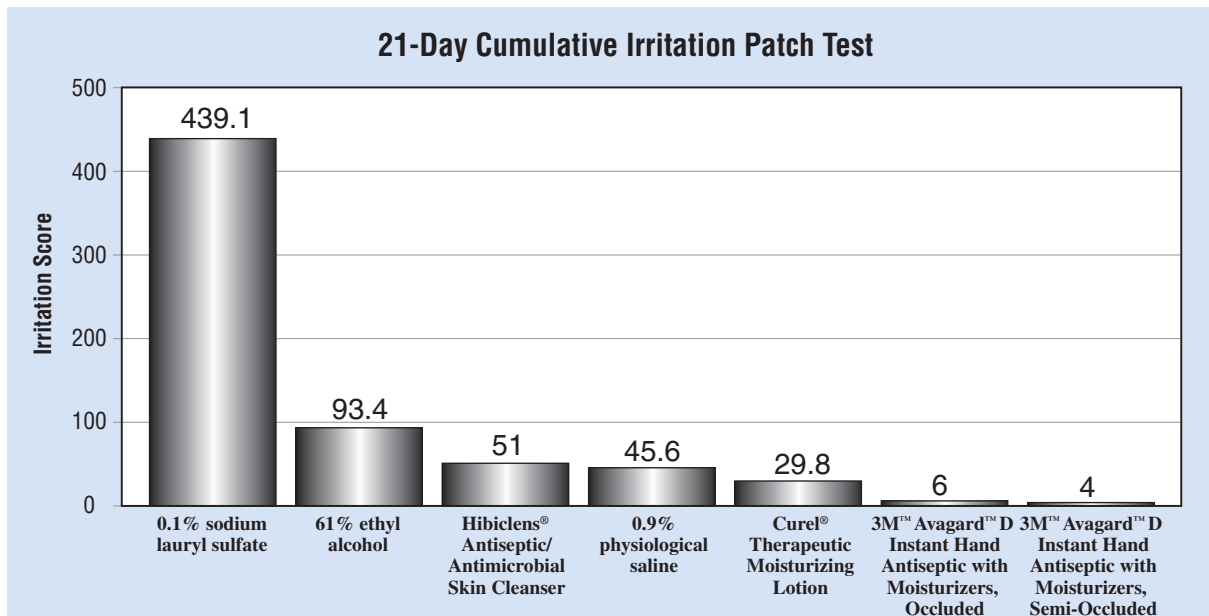
## Human Cumulative Irritation Patch Test

### Objective

The objective of this study was to determine the relative skin irritation potential of 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers (under occluded 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

3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers was classified as a mild material, under occluded and semi-occluded 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 with Moisturizers.

### 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 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers has a potential for contact sensitization.

## Latex Glove Compatibility Study

### Objective

To determine if 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers 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 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers, 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 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers 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

3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers 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.

<sup>1</sup> Data on file, 3M Health Care.

<sup>2</sup> Data on file, 3M Health Care.

<sup>3</sup> Health Canada Infection Control Guidelines: Handwashing, Cleaning, Disinfection, and Sterilization in Healthcare, CCDR1998; 24S8: 1-9.

<sup>4</sup> APIC Guideline for Handwashing and Hand Antisepsis in Health Care Settings, 1995 Larson, E.L.

<sup>5</sup> 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.

<sup>6</sup> CDC - Centers for Disease Control and Prevention. Recommendations and Reports (2002, October). *Guideline for Hand Hygiene in Health-Care Settings*. Vol. 51/No. RR-16, pg. 8.

<sup>7</sup> 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.

### For more information about 3M Health Care Products:

- Contact your local 3M sales representative
- Call 3M Health Care 1 800 364-3577
- Visit our 3M Health Care products website <http://www.3M.com/CA/IP>



Health Care  
3M Canada

Post Office Box 5757  
London, Ontario N6A 4T1

1 800 364-3577 Ontario  
1 800 361-4488 Quebec  
1 800 361-4488 Maritimes  
1 800 661-8126 Western Canada

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.  
3M and Avagard are trademarks of 3M.  
Used under license in Canada.

Printed in Canada © 3M 2005. All rights reserved.  
0510 MS23461E

# Technical Information Bulletin

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

### Introduction

*Destroys bacteria. Not your skin!*

Contains 61% (w/w) (68.5% v/v) ethyl alcohol in an emollient-rich lotion base.

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

### Indications for Use

3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers 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.<sup>1</sup>

CHG (Chlorhexidine gluconate) and Latex Compatible\*<sup>2</sup>  
Use instead of hand washing when soap and water are not readily available or convenient, or between hand washings to kill bacteria.

Use on intact skin that is not visibly soiled with dirt or organic material.

Meets recommendations of LCDC<sup>3</sup>, APIC<sup>4</sup> and CDC<sup>5</sup> Guidelines for Hand Washing/Hand Antisepsis.

### Active Ingredient

- Ethyl Alcohol, 61% (w/w), 68.5% (v/v).

*Contains no fragrance, perfumes, or dyes.*

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



**3M** Innovation

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

## In Vitro Antimicrobial Efficacy

### Objective

The objective of this test was to assess how rapidly 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers [61% (w/w), 68.5% (v/v) ethyl alcohol] kills bacteria.

### Method

3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers was brought in contact with a known population of organisms for a specified period of time at a specified temperature. The activity of the 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers 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

3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers offers fast and effective reduction of a broad spectrum of microorganisms.

### Percent Microbial Kill at 15 and 30 Seconds

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

“The antimicrobial activity of alcohols can be attributed to their ability to denature proteins (destroy microbes). Alcohol solutions containing 60% - 90% alcohol are most effective, and higher concentrations are less potent because proteins are not denatured easily in the absence of water. The alcohol content of solutions may be expressed as percent by weight (w/w), which is not affected by temperature or other variables, or as percent by volume (vol/vol), which can be affected by temperature, specific gravity, and reaction concentration. For example, 70% alcohol by weight is equivalent to 76.8% by volume if prepared at 15°C, or 80.5% if prepared at 25°C. Alcohol concentrations in antiseptic hand rubs are often expressed as percent by volume.”<sup>6</sup>

## In Vivo Antimicrobial Efficacy

Two studies evaluated the antimicrobial effectiveness of 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers 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 Hand Wash Formulations.

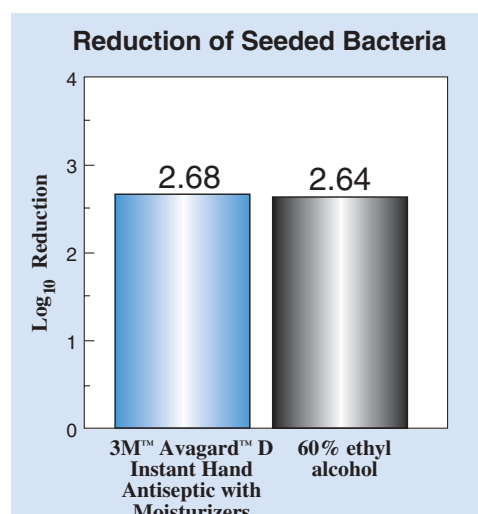
### Single-Wash Healthcare Personnel Hand Wash Study #1

#### Objective

To evaluate the antimicrobial effectiveness of 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers compared to 60% v/v alcohol in reducing transient bacteria, as specified in the Tentative Final Monograph for Health-Care Antiseptic Drug Products (TFM)<sup>7</sup>.

#### 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 hand wash, using either 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers 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, 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers 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 Hand Wash Study #2

#### Objective

The objective of this study was to evaluate the antimicrobial efficacy of 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers compared to Purell® Instant Hand Sanitizer with Moisturizers (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)<sup>7</sup>.

#### Method

This was a single blinded parallel comparison. The hands of fifty-one (51) healthy volunteers were contaminated with *Serratia marcescens* and the baseline level of marker organisms on each volunteer's hands was determined. Following a single hand wash, using either 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers, Purell® Instant Hand Sanitizer with Moisturizers, 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, 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers resulted in a 3.01 log reduction of bacteria on contaminated hands. When tested at equal volumes, 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers showed no significant difference from Purell® Instant Hand Sanitizer with Moisturizers (3.15 log reduction). However against Bacti-Stat® Healthcare Personnel Hand Wash (2.36 log reduction), 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers demonstrated better immediate reduction of seeded bacteria.

**As set forth in the TFM<sup>7</sup>, 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers satisfies the acceptance criterion of a 2 log bacterial reduction following a single wash with a healthcare personnel hand wash.**

**Objective**

The objective of this study was to compare the relative gentleness of 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers to 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 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers applied to one hand randomized according to dominance. The other hand was treated with either Purell® Instant Hand Sanitizer with Moisturizers 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 (1-3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers, 5-Purell® Instant Hand Sanitizer with Moisturizers and 6-water). Dryness scores progressively increased after additional applications of Purell® Instant Hand Sanitizer with Moisturizers and water but not after additional applications of 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers. The last expert grader evaluation each study day showed 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers was significantly ( $p < 0.005$ ) less drying than either Purell® Instant Hand Sanitizer with Moisturizers or water. Similarly, ratings of erythema and tactile roughness showed Purell® Instant Hand Sanitizer with Moisturizers was significantly more irritating than 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers. Subject self-assessments at days 4 and 5 rated 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers significantly ( $p < 0.02$ ) better than both Purell® Instant Hand Sanitizer

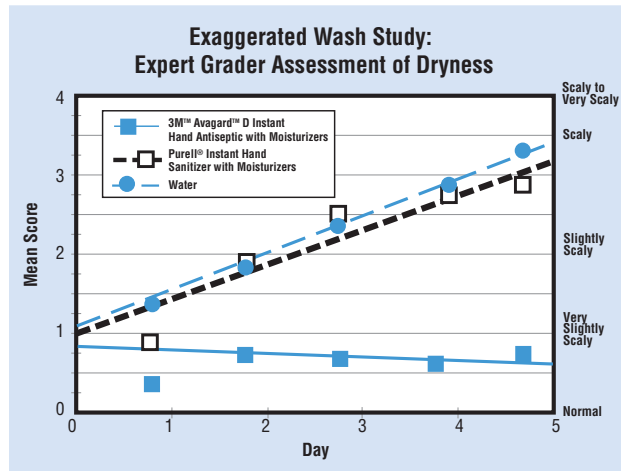


Figure 1

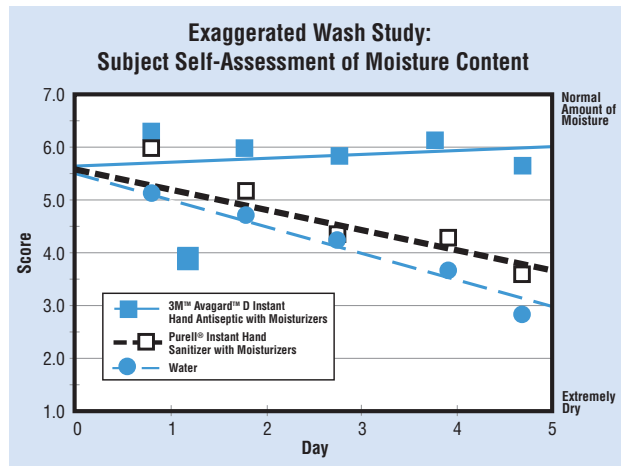


Figure 2

with Moisturizers and water for skin appearance, intactness, moisture, and sensation. Electrical conductance measurements demonstrated that Purell® Instant Hand Sanitizer with Moisturizers or water reduced skin surface hydration while 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers increased skin hydration.

In conclusion, 3M™ Avagard™ D Instant Hand Antiseptic with Moisturizers 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.