3M™ Avagard™ D

(61% w/w ethyl alcohol) Instant Hand Antiseptic with Moisturizers

Defeat bacteria without surrendering your skin.

Safety and Efficacy Information

Lead The Way

3M

Introduction

Destroys bacteria. Not your skin.

Avagard™ D Instant Hand Antiseptic 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 over 99.999% of harmful bacteria in 15 seconds *(in vitro)*.* 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.

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

Drug Facts

Active ingredients **Purpose**

Ethyl Alcohol, 61% w/w ..... Antiseptic

Contains no fragrances or perfumes

Uses: instant healthcare personnel hand antiseptic

• reduces bacteria that potentially can cause disease

• recommended for repeated use

Warnings

For external use only. Flammable, keep away from fire or flame.

When using this product keep out of eyes. If contact with eyes occurs, rinse promptly and thoroughly with water.

Stop use and ask a doctor if significant irritation, or sensitization develops.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Supervise children in the use of this product.

Directions

Apply to clean, dry hands. Use a sufficient amount to thoroughly wet all surfaces of hands and fingers. Rub onto hands until dry.

Other Information

• Store at 20-25°C (68-77°F)

Inactive ingredients beheneth-10, benhenyl alcohol, C20-40 pareth-24, cetyl palmitate, diisoropyl dimer dilinoleate, dimethicone, glycerin, polyethlene glycol, squalane, water

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

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.

3M Internal Data (EM-05-012349)

Table 1: Avagard™ D Instant Hand Antiseptic offers fast and effective reduction against a broad spectrum of microorganisms. Table below lists percent kill of each organism at each time point tested.

Organism	15 sec.	30 sec.	60 sec.
Acinetobacter baumannii, ATCC 19606	>99.9999	>99.9999	>99.9999
Bacteroides fragilis, ATCC 25285	>99.9999	>99.9999	>99.9999
Candida albicans, ATCC 10231	>99.9995	>99.9995	>99.9995
Candida glabrata, ATCC 26512	>99.9999	>99.9999	>99.9999
Enterobacter aerogenes, ATCC 13048	>99.9999	>99.9999	>99.9999
Enterococcus faecalis, ATCC 29212	>99.999	>99.999	>99.999
Enterococcus faecalis (VRE), ATCC 51299	>99.9999	>99.9999	>99.9999
Enterococcus faecium, ATCC 19434	>99.9999	>99.9999	>99.9999
Escherichia coli, ATCC 11229	>99.9999	>99.9999	>99.9999
Escherichia coli, ATCC 25922	>99.9999	>99.9999	>99.9999
Haemophilus influenzae, ATCC 19418	>99.9999	>99.9999	>99.9999
Klebsiella pneumoniae, ATCC 4352	>99.999	>99.999	>99.999
Micrococcus luteus, ATCC 7468	>99.9999	>99.9999	>99.9999
Proteus mirabilis, ATCC 7002	>99.9999	>99.9999	>99.9999
Pseudomonas aeruginosa, ATCC 15442	>99.9999	>99.9999	>99.9999
Pseudomonas aeruginosa, ATCC 27853	>99.9999	>99.9999	>99.9999
Serratia marcescens, ATCC 14756	>99.9999	>99.9999	>99.9999
Staphylococcus aureus, ATCC 6538	>99.9998	>99.9998	>99.9998
Staphylococcus aureus, ATCC 29213	>99.999	>99.999	>99.999
Staphylococcus aureus (MRSA), ATCC 33592	>99.9999	>99.9999	>99.9999
Staphylococcus epidermidis, ATCC 12228	>99.9999	>99.9999	>99.9999
Staphylococcus epidermidis (MRSE), ATCC 51625	>99.999	>99.999	>99.999
Staphylococcus haemolyticus, ATCC 29970	>99.9996	>99.9996	>99.9996
Staphylococcus hominis, ATCC 27844	>99.9996	>99.9996	>99.9996
Staphylococcus saprophyticus, ATCC 15305	>99.999	>99.999	>99.999
Streptococcus pneumoniae, ATCC 33400	>99.9999	>99.9999	>99.9999
Streptococcus pyogenes, ATCC 19615	>99.9999	>99.9999	>99.9999

MRSA — methicillin-resistant *Staphylococcus aureus* MRSE — methicillin-resistant *Staphylococcus epidermidis*
VRE — vancomycin-resistant *Enterococcus*

Three 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 the first two studies 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.

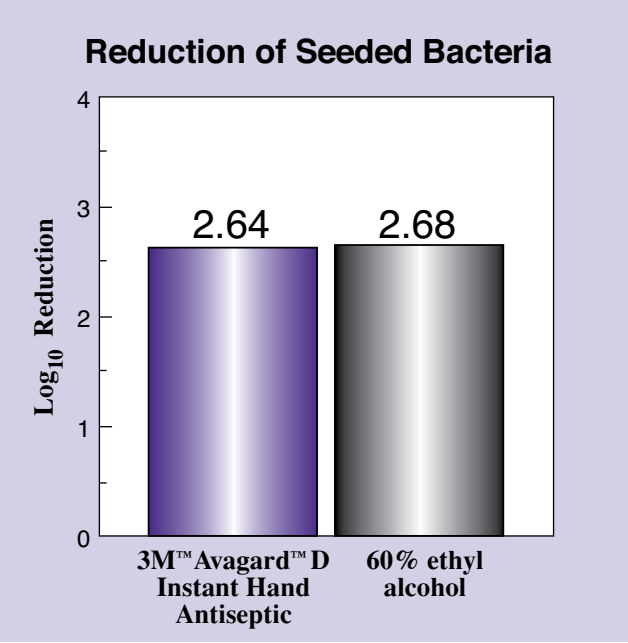
Single-Wash Healthcare Personnel Handwash Study #1

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 2.64-log reduction of bacteria on contaminated hands, with no significant difference from 60% ethyl alcohol (P=0.91).

3M Internal Data (LIMS 8136)

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 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, 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 (P=0.68) 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 significantly better immediate reduction of seeded bacteria (P=0.03).

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.

3M Internal Data (LIMS 8431)

Single-Wash Healthcare Personnel Handwash Study #3 Using New ASTM Method

Objective

The objective of this study was to evaluate the immediate antimicrobial efficacy of Avagard™ D Instant Hand Antiseptic when used in two configurations of application. Testing was performed according to ASTM Standard Test Method E2755-10, *Determining the Bacteria-Eliminating Effectiveness of Hand Sanitizer Formulations Using Hands of Adults*. This new method was specifically designed for antimicrobial efficacy testing of leave-on hand sanitizers by utilizing a smaller volume of a more concentrated marker organism.

Method

This was a single blinded parallel comparison. The hands of twenty (20) healthy volunteers per configuration were contaminated with *Serratia marcescens* and the baseline level of marker organism on each volunteer's hands was determined. Following a single handwash using one of two application configurations of Avagard™ D Instant Hand Antiseptic (1 mL versus 2 mL), the glove juice technique was used to recover the surviving bacteria. Log reductions from baseline were calculated for each application configuration.

Conclusion

After one 1 mL application, Avagard™ D Instant Hand Antiseptic resulted in a 2.06 mean log reduction of bacteria on contaminated hands. After one 2 mL application, a 3.22 mean log reduction was achieved. 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.

3M Internal Data (EM-05-012183)

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 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. Purell® Instant Hand Sanitizer was significantly more irritating than Avagard™ D Instant Hand Antiseptic on days 3-5 for erythema (P=0.007) and on all days for tactile roughness (P<0.002). 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 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.

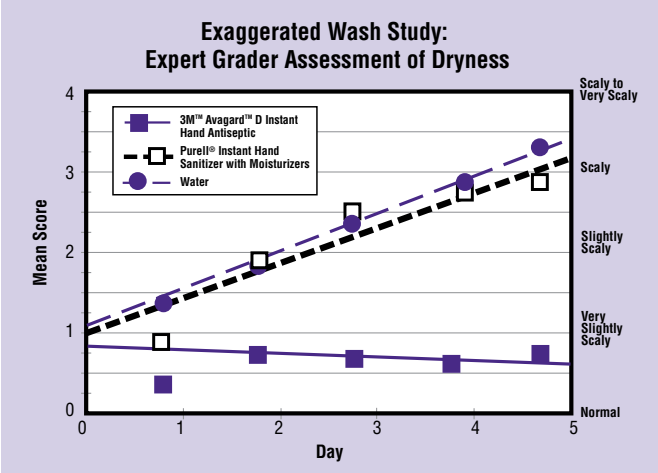


Figure 1

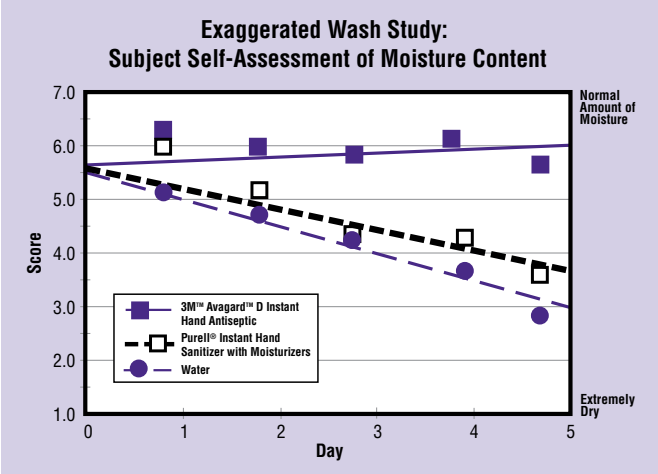


Figure 2

3M Internal Data (LIMS 7780)

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 occlusive and semi-occlusive 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. Using a Fisher's LSD test with an overall of significance of 0.05, the irritation scores were significantly lower than those of the positive control (0.1% sodium lauryl sulfate), the negative control (0.9% physiological saline), and two of the comparison materials (61% ethyl alcohol and Hibiclens® Antiseptic/Antimicrobial Skin Cleanser), but not significantly different from the third comparison material, 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

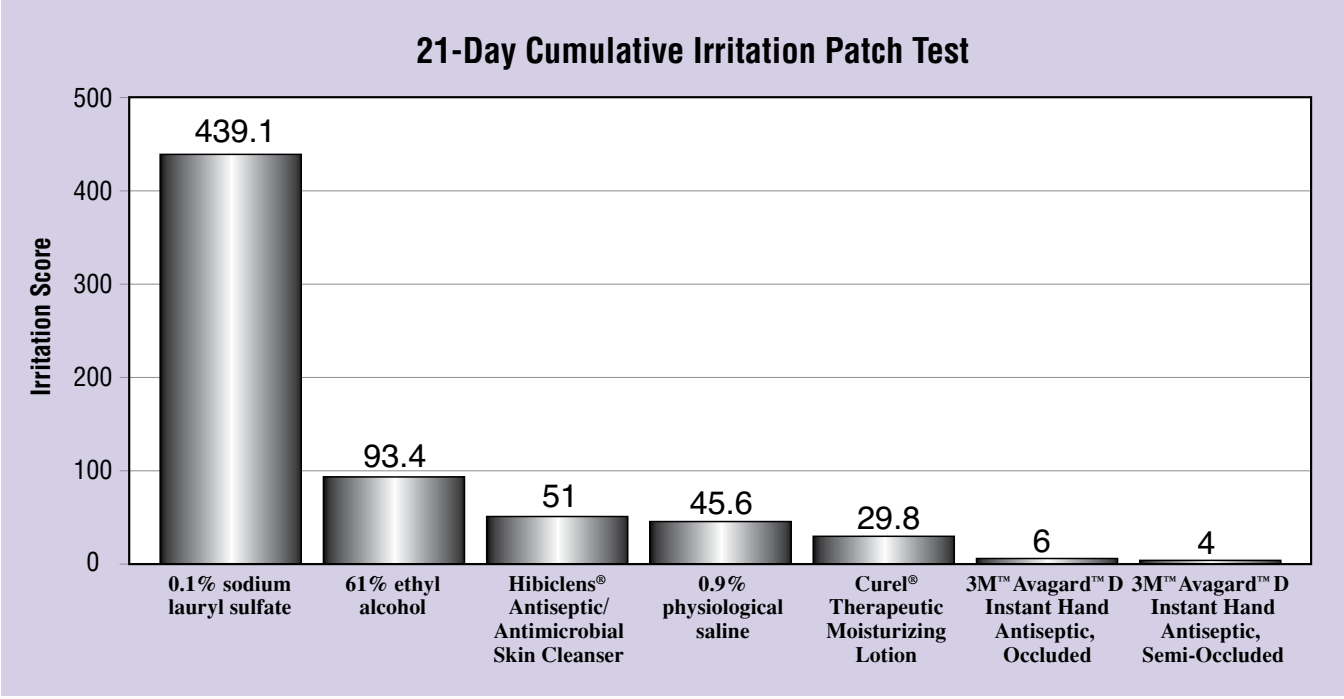
The test article was applied to the upper back of 217 healthy volunteers. The study design consisted of three (3) phases:

- 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.

3M Internal Data (LIMS 7771)



Glove Compatibility Study

Claim

Compatible with latex gloves (Safeskin) and non-latex gloves (Triflex PVC and Elastylon).

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.

3M Internal Data (LIMS 8413)

References

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

2 Centers for Disease Control and Prevention. Guideline for Hygiene in Health-Care Settings: Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. MMWR 2002;51(no. RR-16).

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.

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