

FiteBac® Germicidal Hand Gel Study

Introduction: The routine use of lotions to minimize the development of dermatitis on hands of health professionals that undergo many wash procedures per day has been a component of infection control recommendations for many years. In the past, the primary role for these lotions was to lubricate epithelial tissue and replace emollients that were removed. The overall purpose of this study was to examine antimicrobial properties of **FiteBac® Germicidal Hand Gel** (FiteBac SkinCare, LLC) using the gram-negative bacillus *Serratia marcescens* as an indicator microorganism for effectiveness. Experiments were developed to initially determine the antimicrobial activity following bacterial challenge on hands coated with the hand gel. The product was also tested for extended effectiveness during prolonged glove use by volunteers. Finally, the ability of **FiteBac® Germicidal Hand Gel** to exhibit a demonstrable antibacterial effect following repeated hand washing was investigated.

Experimental Design:

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Hands of potential volunteers for the investigation were initially screened for any observable skin conditions or injuries (i.e., broken skin) that could prevent them from participation in the project. The condition of the volunteers' hands was also visually evaluated throughout the three phases of the study. Four (4) volunteers were then instructed to wash their hands with a non-antimicrobial liquid soap and water for one minute to initially cleanse the skin before application of the experimental gel. A small amount (dime size) of **FiteBac Germicidal Hand Gel** was then applied onto the participants' hands and rubbed vigorously into the skin. Immediately after this application, a 2 x 2" square section of the dorsal surface of each hand was swabbed with a 1:100,000 dilution (left hand) and a 1:1,000,000 dilution (right hand) of a 24-hour broth culture of the red-pigmented bacterial species, *S. marcescens*. These two bacterial dilutions were used following multiple preliminary experiments that were carried out to determine concentrations of *S. marcescens* that would reproducibly challenge hand gel activity. The resultant concentrations of *S. marcescens* used to challenge hands were approximately 1×10^5 bacteria/mL (left hand) and 1×10^4 bacteria/mL (right hand), respectively. Applied bacterial suspensions were allowed to dry before proceeding with further testing. Subsequently, antibacterial activity of **FiteBac Germicidal Hand Gel** as determined by the presence of *S. marcescens* at the application sites was assayed by swabbing the 2 x 2" test areas with sterile cotton swabs moistened in sterile trypticase soy broth. Sample intervals of 1 minute, 30 minutes, 2, 4, 6, and 8 hours were utilized. Collected samples were streaked onto trypticase soy agar plates and incubated aerobically at room temperature for 48-72 hours. Incubation of *S. marcescens* under these conditions allowed for both microbial growth and red pigment production by the bacteria.

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Four volunteers initially prepared their hands as described above. **FiteBac Germicidal Hand Gel** was applied to both hands and allowed to dry, followed by application of the 1:100,000 and 1:1,000,000 dilutions of cultured *S. marcescens*. Hands were allowed to dry and zero minute control samples were taken before proceeding. Participants then washed their hands for 15 seconds with a non-antimicrobial soap after sampling at designated periods of 0 (control) minutes, 30 minutes, 2, 4, 6 and 8 hours. Samples were taken from the *S. marcescens*-seeded hand sites using sterile broth moistened cotton swabs, cultured on trypticase soy agar plates, incubated, and observed for bacterial growth as described above.

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3

The participants washed their hands as described above prior to the glove use portion of the investigation, followed by application of **FiteBac Hand Gel**. The *S. marcescens* test dilutions were swabbed onto the right and left hand test sites, respectively. Participants then donned nitrile gloves and continued to wear them for one hour while performing routine work tasks. At the end of this interval gloves were removed, samples collected from test sites using moistened cotton swabs, and trypticase soy agar plates seeded with material from the skin. Prepared culture plates were incubated at room temperature for 48-72 hours prior to observation for red-pigmented *S. marcescens* colonies.

Results:

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Sixteen (16) test samples from each *S. marcescens* dilution (1:100,000 and 1:1,000,000) were assayed. Culture findings are presented in Table 1. All *S. marcescens* control cultures collected without exposure to the hand gel yielded confluent bacterial growth. With regard to the 1-minute samples, 25/32 cultures were positive for red-pigmented colonies. These showed higher levels of bacterial growth on each plate than was detected for later experimental collection intervals. In most cases the pigmented growth for the one minute-exposure plates was similar in intensity per plate to that noted for the positive control plates, or was slightly less (Figures 1 and 2). For all other test cultures where positive growth was observed, the presence of bacteria cultured for these intervals was considerably less (Figure 3). It was interesting to note that as the time intervals of skin exposure to **FiteBac Hand Gel** increased, the resultant detection of *S. marcescens* colonies decreased, until by six hours none of the test cultures yielded red-pigmented colonies (0/32) (Figure 4). No hand dermatitis problems were noted for any of the volunteers.

Table 1. Effect of **FiteBac Hand Gel** with Repeated Bacterial Exposure.

Sample Time	1:100,000 dilution	1:1,000,000 dilution
Positive Controls	16/16	16/16
1 min	16/16	9/16
30 min	4/16	2/16
2 hours	3/16	0/16
4 hours	4/16	0/16
6 hours	0/16	0/16
8 hours	0/16	0/16



Figure 1: Positive *S. marcescens* control culture.

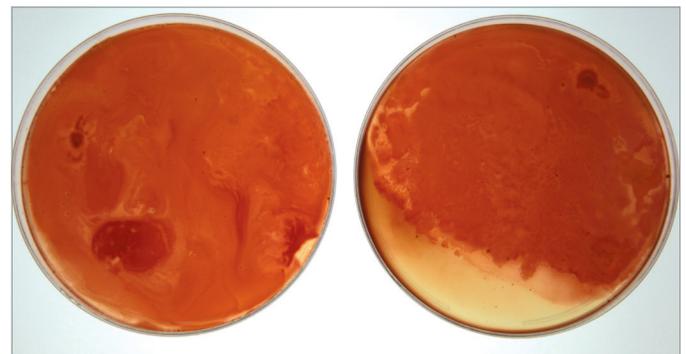


Figure 2: *S. marcescens* growth after 1 minute Exposure to FiteBac Hand Gel.



Figure 3: *S. marcescens* growth after 4 hours Exposure to FiteBac Hand Gel.

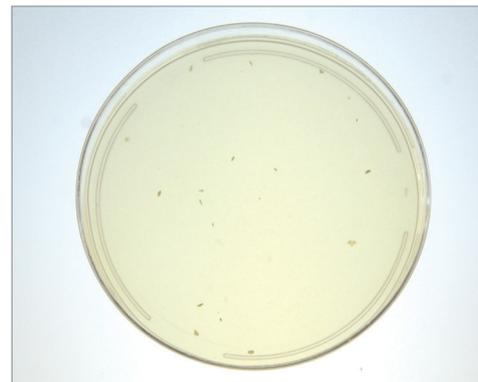


Figure 4: Antimicrobial Effect of **FiteBac Hand Gel** after 6 hours of Bacterial Exposure.

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Eighteen (18) test samples of each dilution were completed for Phase 2 and the observed results are presented in Table 2. The zero-minute time interval represented the only sampling before any hand washing had occurred. The observed results were comparable to the one-minute data obtained in Phase 1, in that all test samples produced positive results but the per plate quantity of growth was much less than that observed on the corresponding positive controls. All other positive test cultures observed at later time intervals produced considerably less pigmented growth, much like what was seen for cultures in Phase 1. No hand dermatitis problems were noted for any of the volunteers.

Table 2. Effect of Hand Gel with Repeated Handwashing and Bacterial Exposure.

Sample Time	1:100,000 dilution	1:1,000,000 dilution
Control plates	18/18	18/18
0 min	17/18	5/18
30 min	3/18	0/18
2 hours	1/18	0/18
4 hours	0/18	0/18
6 hours	0/18	0/18
8 hours	0/18	0/18

PHASE

3

All except one (15/16) experimental cultures from samples taken after removal of gloves were negative for red-pigmented bacteria (Table 3, Figure 5). In contrast, in a separate positive control assay, a participant applied bacteria only and wore gloves for one hour without the use of **FiteBac Hand Gel**. Resultant cultures from control test sites were positive (4/4) (Fig 6). The qualitative presence of *S. marcescens* in these controls was much less than that found for control plates using diluted bacteria only (16/16). No hand dermatitis problems were noted for any of the volunteers.

Table 3. Effect of Hand Gel during Glove Use.

Sample Time	1:100,000 dilution	1:1,000,000 dilution
Control plates	16/16	16/16
1 hour	1/16	0/16

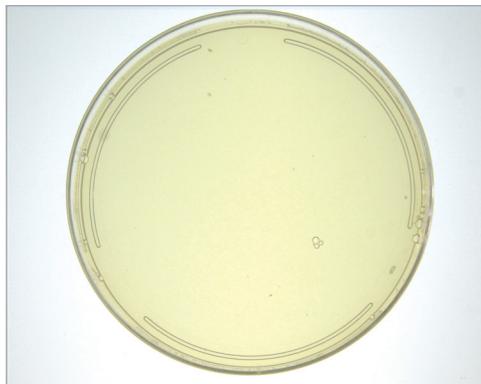


Figure 5: Lack of *S. marcescens* Growth Following FiteBac Hand Gel Application and Prolonged Glove Use.



Figure 6: Positive *S. marcescens* Culture without FiteBac Hand Gel.

Summary:

The present investigation demonstrated that **FiteBac Hand Gel** provided an antimicrobial benefit. Laboratory testing with *S. marcescens* demonstrated that the gel was effective in inhibiting test bacteria applied onto the skin during multiple hand wash procedures and prolonged wearing of gloves. Additionally, none of the participating volunteers demonstrated any irritation dermatitis symptoms with exposure to the FiteBac Hand Gel.

