Biological Consulting Services
of North Florida, Inc.

December 20, 2012

Global Health
Mr. Al Cellura
Global Health Products
1099 Jay Street, Suite 100E
Rochester, NY 14611

Re: Preliminary antimitotic efficacy study of the provided "Prep-It" solution against *Trichophyton mentagrophytes.*

Dear Mr. Cellura,

We have completed the antimicrobial efficacy screening study on the supplied "Prep It" solution. The study was performed to evaluate the potential efficacy of the solution. Testing was done according to the protocol that is regularly used to assess antimicrobial efficacy of spray disinfectants. The protocol used is based on an adaptation of the standard method described in AOAC Official Method 961.02 (Germicidal Spray Products as Disinfectants) and from ASTM E2111-00 (Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides).

In the following pages, you will find a summary of the methodology used and the results of our analysis. Should you have any questions or concerns please do not hesitate to contact me.

Best Regards,

George Lukasik, Ph.D.
Laboratory Director

BCS LABORATORIES, INC.-GAINESVILLE
4609 NW 6TH STREET, BLDG A, GAINESVILLE, FLORIDA 32609
TEL. (352) 377-9272, FAX. (352) 377-5630
WWW.MICROBIOSERVICES.COM
FL DOH Laboratory #E82924, EPA# FL01147

Challenge Microbial Culture Preparation and Enumeration

Trichophyton mentagrophytes (ATCC 9533) stock culture was obtained from Microbiologics® and maintained as per suppliers' recommendations. Cultures used in the study were less than two passage from original stocks. Working cultures were propagated on Sabouraud Dextrose Agar (SDA, Neogen, MI).

For challenge experiments, spores were produced using ASTM E2111-00 (Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal and Sporicidal Potencies of Liquid Chemical Germicides). Briefly, a 100 ml of Sabouraud Dextrose Broth (SDB, Neogen, MI) culture from a colony off a purified plate stock was grown for 4 days at 25º C and rotary agitated. The fungal suspension was homogenized until well dispersed and inoculated onto multiple Sabouraud Dextrose Agar (SDA, Neogen) plates. The plates were incubated at 25°C for 7 days. The fungal growth on the plates was then harvested using Phosphate Buffered Saline (PBS). The liquid growth harvest was homogenized using glass beads and the solution was then filtered through a gauze pad. It was then mixed till homogenous prior to use. The filtrate was used within 24 hours of harvest.

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The number of viable microbial species was enumerated as colony forming units (cfu) using spread plating onto SDA. Serial tenfold dilutions were performed in Phosphate Buffered Saline (PBS, Remel Inc., USA). Inoculated plates were incubated aerobically at 25º C for 5-7 days and the resulting colonies were enumerated.

Supplied Disinfectant:

On October 31, 2012 a container labeled "Prep-It" was received at BCS Laboratory-Gainesville from Global Health Products and assigned BCS ID # 1210109.

Challenge Study: November 16, 2012

The supplied solution was placed in the manual aerosol sprayer. The temperature of the disinfectant prior to application and during disinfection efficacy testing was maintained at 22±1°C. Twenty microliters of the microbial suspension was pipetted onto sterile 20 x 26 mm glass slides (Allegiance, USA). A total of six slides were inoculated; 4 slides were used for the spray disinfection and 1 slide was used as untreated positive growth control. Additionally, one un-inoculated slide was used as a negative growth control. The inoculum was allowed to dry at 22-24°C for 35 minutes. The inoculated slides and the uninoculated control slide were sprayed for 8 seconds from a distance of 10" with the provided "Prep-It" solution. The slides were evenly saturated with liquid. The positive growth control slide was not exposed to the spray disinfectant. The slides were allowed to incubate at 22°C for 10 minutes. Time measurement was conducted with a NIST

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traceable timer. Following, each slide was aseptically removed, the excess fluid was drained, and the slide was placed into a sterile 50 ml sterile polypropylene tube conical bottom centrifuge tube. Each tube contained 10 milliliters of D/E Neutralizing Broth (Neogen, MI). The tubes were agitated for 15 minutes on a horizontal plate mixer at a medium speed (RotoMix, Barnstead/ Thermolyne Inc., USA). The sprayed uninoculated negative control slide and the inoculated and unsprayed positive control slide were treated as described above. Ten fold dilutions of the recovered microbial suspensions were performed in PBS. The number of viable microbial species in each of the tubes was enumerated by spread plating onto SDA as described. All analysis for each sample was conducted in duplicates.

All data are summarized in the following table. The results presented pertain only to the samples analyzed and identifier number(s) indicated. The data provided is strictly representative of the study conducted using the material provided and its (their) condition at the time of test. The study and data obtained under the laboratory conditions may not be representative or indicative of a real life process and/or application. Positive, negative, and neutralization controls were performed as outlined in the method and as per Good Laboratory Practices. All analyses were performed in accordance to laboratory practices and procedures set-forth by our NELAC accreditation standards (ISO 17025) unless otherwise noted.

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Table 1. The efficacy of provided "Prep-It" (BCS 1210109) solution on *Trichophyton mentagrophytes* as determined by the screening study based on adaptation of AOAC Official Method 961.02 (Testing of Germicidal Spray Products as Disinfectants).

Treatment	Average number of recovered *Trichophyton mentagrophytes* (cfu/ml)*	Average Percent Reduction
Untreated Control (initial)	7.1×10^4	Not Applicable
Slide 1	<1.0**	>99.998%
Slide 2	<1.0**	
Slide 3	<1.0**	
Slide 4	<1.0**	

*The number of viable microbial colonies was determined by spread plating onto SDA (Neogen, MI). Plates were incubated at 26.5º C for 5-7 days.

** No microbial colonies were observed on any of the plates.

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