



MICROBIOLOGICAL REPORT

Private Label Partners, Inc.
 Attn: Dhan Mhaskar, Ph.D.
 547 N. Fairview Street
 Santa Ana, CA 92703

Report Date: 09/17/09
Date Received: 09/08/09
Date Completed: 09/14/09
Project #: 633842
P.O.# : Not Specified
Reference #: 6185-009, 013

Page 1 of 2

SAMPLE DESCRIPTION

| | | | |
|---------------------------|---------------------------------------|---------------------|-----------------------|
| <u>ACCESSION #</u> | <u>SAMPLE</u> | <u>LOT #</u> | <u>BATCH #</u> |
| 633842 | Physicians Recommended Hand Sanitizer | 924499 | Not Specified |

| | |
|-------------------------------|-----------------------------|
| <u>TEST PERFORMED:</u> | <u>BTS METHOD #:</u> |
| Time Kill/Log Reduction | M213.R04 |

The log reduction is used to determine the effectiveness of a product at reducing a specific microorganism population.

The organisms were prepared by inoculating the surface of tryptic soy agar slants. The microorganisms were incubated at 32.5 ± 2.5°C for 24 hours. Following the incubation period the slants were washed with sterile Phosphate Buffered Saline (PBS) to harvest the microorganisms. The microbial suspension was adjusted to approximately 10⁷ colony forming units (CFU) per mL and labeled as the stock suspension.

The microorganism to be tested, 20 mL of test product and 20 mL of PBS was added into separate sterile centrifuge tubes. Each 20 mL sample of test product and PBS was inoculated with approximately 0.2 mL of the 10⁷ CFU/mL suspension. This inoculum resulted in approximately 10⁵-10⁶ CFU/mL into the product and PBS control.

At the time intervals of 30 seconds, 1 minute, and 5 minutes, 1.0 mL from the inoculated test product was taken and placed into 9.0 mL of neutralizing broth (1:10 dilution). Additional 1:10 serial dilutions were prepared using neutralizing broth to achieve 1:100 and 1:1000 dilutions.

One milliliter from each dilution was plated in duplicate and melted tryptic soy agar with polysorbate 80 and lecithin was added as the growth medium for the organisms. The plates were incubated at 35 ± 2°C for a minimum of 48 hours. The same procedure was repeated for the Phosphate Buffer Saline control. After the incubation period, all plates were counted to determine the number of microorganisms remaining at each time point.

RESULTS:

Escherichia coli ATCC# 8739

| EXPOSURE | CONCENTRATION OF ORGANISM | | | | % REDUCTION | | LOG REDUCTION | |
|-----------------|----------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| | (CFU/mL) | | | | | | | |
| | <u>CONTROL</u> | <u>PRODUCT</u> | <u>CONTROL</u> | <u>PRODUCT</u> | <u>CONTROL</u> | <u>PRODUCT</u> | <u>CONTROL</u> | <u>PRODUCT</u> |
| TIME | | | | | | | | |
| Initial | 1.6E6 | 1.6E6 | N/A | N/A | N/A | N/A | N/A | |
| 30 sec. | 2.2E5 | <10 | 86.3 | 100.0 | 0.9 | 5.2 | | |
| 1 min. | 1.5E5 | <10 | 90.6 | 100.0 | 1.0 | 5.2 | | |
| 5 min. | 1.8E5 | <10 | 88.8 | 100.0 | 0.9 | 5.2 | | |

Pseudomonas aeruginosa ATCC# 9027

| EXPOSURE TIME | CONCENTRATION OF ORGANISM (CFU/mL) | | % REDUCTION | | LOG REDUCTION | |
|------------------|---------------------------------------|---------|-------------|---------|---------------|---------|
| | CONTROL | PRODUCT | CONTROL | PRODUCT | CONTROL | PRODUCT |
| | Initial | 7.3E5 | 7.3E5 | N/A | N/A | N/A |
| 30 sec. | 2.1E5 | <10 | 71.2 | 100.0 | 0.5 | 4.9 |
| 1 min. | 2.5E5 | <10 | 65.8 | 100.0 | 0.5 | 4.9 |
| 5 min. | 1.8E5 | <10 | 75.3 | 100.0 | 0.6 | 4.9 |

Staphylococcus aureus ATCC# 6538

| EXPOSURE TIME | CONCENTRATION OF ORGANISM (CFU/mL) | | % REDUCTION | | LOG REDUCTION | |
|------------------|---------------------------------------|---------|-------------|---------|---------------|---------|
| | CONTROL | PRODUCT | CONTROL | PRODUCT | CONTROL | PRODUCT |
| | Initial | 9.8E5 | 9.8E5 | N/A | N/A | N/A |
| 30 sec. | 1.1E5 | <10 | 88.8 | 100.0 | 0.9 | 5.0 |
| 1 min. | 1.0E5 | <10 | 89.8 | 100.0 | 1.0 | 5.0 |
| 5 min. | 9.6E4 | <10 | 90.2 | 100.0 | 1.0 | 5.0 |

Klebsiella pneumonia ATCC# 10031

| EXPOSURE TIME | CONCENTRATION OF ORGANISM (CFU/mL) | | % REDUCTION | | LOG REDUCTION | |
|------------------|---------------------------------------|---------|-------------|---------|---------------|---------|
| | CONTROL | PRODUCT | CONTROL | PRODUCT | CONTROL | PRODUCT |
| | Initial | 1.6E5 | 1.6E5 | N/A | N/A | N/A |
| 30 sec. | 1.5E5 | <10 | 6.3 | 100.0 | 0.0 | 4.2 |
| 1 min. | 1.4E5 | <10 | 12.5 | 100.0 | 0.1 | 4.2 |
| 5 min. | 1.6E5 | <10 | 0.0 | 100.0 | 0.0 | 4.2 |

DATA CALCULATION:

The concentration of each microorganism for the control and product is listed for each interval. These numbers are expressed in terms of scientific notation. The next heading represents the "Log Reduction" information for each time point. The calculation is used to express the change (reduction or increase) of the microorganism population relative to a starting inoculum.

The Log₁₀ reduction is calculated as follows:

$$\text{Log}_{10}(\text{initial count}) - \text{Log}_{10}(\text{x time interval}) = \text{Log}_{10} \text{reduction}$$

DISCUSSION:

The minimum bactericidal concentration is defined as 3 log reduction from the initial inoculum¹. The product did achieve more than 3 log reduction at the 30 seconds, 1 minute, and 5 minute time intervals for all organisms.

CONCLUSION:

The results indicate that the Physicians Recommended Hand Sanitizer, Lot # 924499 does have antibacterial activity against all the organisms at 30 seconds, 1 minute, and 5 minutes.



Stephanie Turcios, M.S.

Microbiology Assistant Manager

¹ Disinfection, Sterilization, and Preservation Fourth Edition, Seymour S. Block, pg. 1035