Micro Quality Labs

3200 N. San Fernando Blvd. • Burbank, California 91504
(818) 845-0070 • Fax: (818) 845-0030
E-Mail: MicroQualityLabsInc.@sbcglobal.net

MICROBIOLOGICAL REPORT

Business Name: Pinnaclife
Business Address: 59 Second Street
Coralville, IA 52241

Report Date: 07/10/12
Date Received: 07/06/12
Date Completed: 07/06/12

SAMPLE DESCRIPTION:

ACCESSION #	SAMPLE:	LOT # / BATCH#
Project #4092	Wound Shield	MD-G36-096, 05/22/12

TEST PERFORMED:
Bacterial Reduction –
Reference AOAC

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

Escherichia coli was prepared by inoculating the surface of TSA slants. Each microorganism was then incubated at 30 to 35°C for 18 to 24 hours. Following the incubation period the slants were washed with sterile Serological Saline Solution to harvest the microorganisms. Using Culti-Loops microorganisms were grown and adjusted to 10^8 (cfu) colony forming units per mL and used as a stock suspension. An additional 1:10 dilution of the stock suspension was made using Serological Saline Solution to achieve a concentration of approximately 10^7 CFU per mL.

For the microorganism to be tested, 20 mL of test product and 20 mL of Serological Saline Solution was added into separate sterile tubes. Each 20mL sample of test product and Serological Saline Solution was inoculated with 0.2 mL of the 10^7 CFU/mL suspensions. These inoculums resulted in approximately 10^6 CFU/mL into the product and Serological Saline Solution control.

At the time intervals of 30 seconds, 1 minute and 3 minutes, 1.0 mL from the inoculated test product was taken and placed into 9.0 mL of Modified Letheen Broth (1:10 Dilution). Additional 1:10 serial dilutions were prepared using neutralizing broth to achieve 1:100 and 1:1000 dilutions.

1 mL from each dilution was plated in sterile Petri dishes and melted TSA agar was added as the growth medium for bacterial organisms.

The bacterial plates were incubated at 30 to 35°C for 48 hours. The same procedure was repeated for the Serological Saline Solution control. After the incubation period, all plates were counted to determine the number of microorganisms remaining at the various time points.

Micro Quality Labs Inc.

3200 N. San Fernando Blvd. • Burbank, California 91504
(818) 845-0070 • Fax: (818) 845-0030
E-Mail: MicroQualityLabsInc. @sbcglobal.net

MICROBIOLOGICAL REPORT

Pinnaclife
Project #: 4092

RESULTS:
***Escherichia coli** ATCC# 11229*

EXPOSURE TIME	CONCENTRATION OF ORGANISM (CFU/mL)		% REDUCTION		LOG REDUCTION	
	CONTROL	PRODUCT	CONTROL	PRODUCT	CONTROL	PRODUCT
INITIAL	3.40×10^5					
30 seconds	3.40×10^5	1.70×10^5cfu/gm/ml	N/A	75.0%	0.00	0.60
1 minute	3.40×10^5	5.60×10^4cfu/gm/ml	N/A	97.7%	0.00	1.65
3 minute	2.80×10^5	<10cfu/gm/ml	11.1%	99.9%	0.05	N/A

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 two headings represent the "% reduction" and "Log Reduction" information for each time point. Both calculations are used to express the change (reduction or increase) of the microorganism population relative to starting inoculums.

$$\% \text{ Reduction} = \frac{\text{Initial Count} - \text{Count at x time interval}}{\text{Initial Count}} \times 100$$

For example: % Reduction for *Control.*

$$\frac{3.40 \times 10^5 - 2.80 \times 10^5}{3.40 \times 10^5}$$

The log reduction is calculated as follows:
Log 10 (initial count) – Log10 (x times interval) = Log reduction

For example: Log 10 (3.40×10^5) – Log10 (2.80×10^5) = 5.25-5.20 = 0.05 log reduction

Discussion:
The minimum bactericidal concentration is defined as 99.9% decrease (3 log) in the initial inoculums. The test product had no counts for growth when exposed to *Escherichia coli* after 3 minute.

Conclusion:
The results indicate that Wound Shield has 99.9% log reduction for *Escherichia coli* at 3 minute of contact time.

The aforementioned results on this report are representative of the samples submitted and may not be indicative of the entire manufacture, batch, and/or lot. Applicable current GMP's shall always be used when sampling. GLP's shall always be practiced by Micro Quality Labs to ensure the most accurate results.

Approved: _____ Date: 7/10/12
Karine Aylozyan
Senior Microbiologist/Q.A. Coordinator

_____ Date: 7/10/12
Germina Ratcauz
Senior/Microbiologist