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April 20, 2007

First Fishery Development
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107664-665

Attn: Mr. Richard Lentz

RE: **PRESERVATIVE/EFFECTIVENESS (P/E STUDY)**
A. EARACHE REMEDY - 1/2 FLUID OUNCE LOT 6M17 3/08
B. DIAPER RASH - 2 FLUID OUNCE LOT T51 11/08

The above samples were submitted to determine the effectiveness of the antimicrobial agent. Prior to inoculating the samples with known organisms, the initial microbial load was determined. The presence of viable organisms prior to inoculation is already an indication of its antimicrobial effectiveness. Both samples were absent of any viable organisms.

SAMPLE PREPARATION

According to USP 24 Reference Method <51>, E. coli ATCC 8739, Pseudomonas aeruginosa ATCC 9027, Staph aureus ATCC 6538, Candida albicans ATCC 10231 and Aspergillus niger ATCC 16404 will be inoculated to the Earache Remedy and Diaper Rash Spray to yield approximately 1×10^5 to 1×10^6 organisms per ml product with the exception of Aspergillus which had initial concentration of 1×10^4 .

0.15 ml of each inoculum was aseptically added to the Earache Remedy and 0.35 was each inoculum to 30 ml of Diaper Rash and immediately shaken to evenly distribute the organisms in solution. For Time 0, 6 Hr and 24 r, the samples were plated at 1:1000, 1:10000 and 1:10,000 dilution in anticipation of the survival of the designated organisms. In addition, 30 ml of sterile saline was also inoculated to run in parallel with the sample. This will determine the viability of each organism throughout the study.

The inoculate sample was plated again at Day 7, Day 14, Day 21, and Day 28. The results are listed in the following pages.

OBSERVATIONS

This initial number of organisms for E. coli, Staph, Pseudomonas, Candida and Aspergillus were detectable immediately after inoculation at level for 10^2 to 10^4 . The same organisms were undetectable at 6 Hr til the end of the study. The saline blank for each organisms is within the expected range of 1×10^5 to 1×10^6 .

Additional study was requested to narrow the time frame of the antimicrobial activity in both samples. Samples were inoculated in the same manner and plated at 1 minute, 1 hour and 2 hours. The results are also listed in the following pages.

CONCLUSION

The submitted sample me the requirements for antimicrobial effectiveness as stated in USP 24 <51>. The criteria are as follows:

Bacteria (E. coli, Pseudomonas & Staph)

Not less than a 1 log reduction from the initial calculated count at Day 7 and not less than 3.0 log reduction from the initial count at Day 14 and no increase from Day 14-Day 28

Yeast/Mold (Candida & Aspergillus)

No increase from the initial calculated count at Day 7, Day 14 and Day 28

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TABLE I CHALLENGE STUDY OVER 28 DAYS

A. EARACHE REMEDY 1/2 FLUID OUNCE LOT 6M17 3/08

Initial Microbial Load	No Growth						
CHALLENGE ORGANISMS	Time 0	6 Hrs	24 Hrs	Day 7	Day 14	Day 21	Day 28
E. coli	1.5×10^4	<1000	<1000	<100	<100	<100	<100
Pseudomonas	<1000	<1000	<1000	<100	<100	<100	<100
Staph	6.1×10^5	<1000	<1000	<100	<100	<100	<100
Candida	3.2×10^5	<1000	<1000	<100	<100	<100	<100
Aspergillus	4.0×10^4	1,000	<1000	<1000	<1000	<1000	<1000

B. DIAPER RASH - 2 FLUID OUNCE LOT T51 11/08

Initial Microbial Load	No Growth						
CHALLENGE ORGANISMS	Time 0	6 Hrs	24 Hrs	Day 7	Day 14	Day 21	Day 28
E. coli	3.0×10^6	<1000	<1000	<100	<100	<100	<100
Pseudomonas	4.2×10^6	<1000	<1000	<100	<100	<100	<100
Staph	9.2×10^6	<1000	<1000	<100	<100	<100	<100
Candida	9.0×10^6	<1000	<1000	<100	<100	<100	<100
Aspergillus	3.0×10^4	1.9×10^4	<1000	<100	<100	<100	<100

C. SALINE

CHALLENGE ORGANISMS	Time 0	6 Hrs	24 Hrs	Day 7	Day 14	Day 21	Day 28
E. coli	6.9×10^6	-	6.0×10^6	5.8×10^6	5.5×10^6	3.8×10^6	1.6×10^6
Pseudomonas	1.3×10^7	-	1.0×10^7	4.0×10^6	3.5×10^6	5.0×10^6	6.0×10^6
Staph	9.4×10^6	-	6.0×10^6	3.9×10^6	2.6×10^6	2.0×10^6	1.0×10^6
Candida	1.5×10^6	-	2.0×10^6	2.9×10^6	1.4×10^6	2.2×10^6	2.6×10^6
Aspergillus	5.5×10^4	1.9×10^4	1.8×10^4	1.0×10^4	1.1×10^4	9.0×10^3	1.0×10^4

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TABLE II - CHALLENGE STUDY OVER A TWO HOUR PERIOD

A. EAR REMEDY

STANDARD PLATE COUNT

	1 Minute	1 Hour	2 Hours
E. coli	<100	<100	<100
Pseudomonas	<100	<100	<100
Staph	<100	<100	<100
Candida	<100	<100	<100
Aspegillus	230,000	28,000	16,000


B. DIAPER RASH

E. coli	3,500,000	470,000	<100
Pseudomonas	630,000	23,000	46,000
Staph	400,000	420,000	1,800
Candida	420,000	16,000	<100
Aspergillus	50,000	23,000	10,000

INOCULATED SALINE

E. coli	-	-	15,000,000
Pseudomonas	-	-	1,800,000
Staph	-	-	8,700,000
Candida	-	-	4,600,000
Aspergillus	-	-	170,000

Reported By:
ANRESKO, INC.


Laila Lam
Microbiologist

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