Antimicrobial Preservative Effectiveness Test/ Category 1C

Conducted by Bioscreen Testing Service, Inc. 3892 Del Amo Boulevard, Ste, G-5, Torrance, CA

Report Date: 08/04/99   Project #   83454
Date received: 06/25/99   Reference#   738-135
Date test completed: 08/04/99

What the test means:

The Preservative Effectiveness Test demonstrates the effectiveness of a substance— when used as a preservative or additive— to stop the growth of such pathogenic organisms as E. coli, Aspergillus niger, Candida albicans, Pseudomonas aeruginosa, and Staphylococcus aureus.

Sample Description: ACC#: 83454

Sample:	Test Performed:	BTS Method:	Reference:	Lot:
Cellfood®	Pres/Effect. Test	M101.R2	USP 23, 8th sup.	ROM508 exp 2/2009

Sample preparation:

The following organisms— *Aspergillus niger, Candida albicans, Escherichia coli, Pseudomonas aeruginosa, and Staphylococcus aureus*— are used to challenge the specimen for twenty-eight (28) days. Microorganism survival is monitored at fourteen (14) and twenty-eight (28) day intervals.

Results: Table Summary

Micro Organism	Initial Inoculum/gm	Colony forming units/ gm		Log reduction	
		14 days	28 days	14 days	28 days
A. niger	4.8×10^5	<10	<10	4.7	4.7
B. albicans	3.2×10^5	<10	<10	4.5	4.5
E. coli	1.2×10^5	<10	<10	5.0	0.0
P. aeruginosa	6.7×10^5	<10	<10	4.8	0.0
S. aureus	7.3×10^5	<10	<10	4.9	0.0

Interpretation:

For Category 1C Products, the preservative is effective in the product examined if:
a)   Not less than or equal to 1.0 log reduction from the inital count at 14 days, and no increase* from the 14 day count at 28 days, is observed in the bacterial samples.
b)   No increase* from the inital calculated count at 14 and 28 days is observed in the yeast and mold samples.;
*No increase is defined as not more than 0.5 $\log_{10}$ unit higher than the previous value measured.

Conclusion:

The above test results meet the current USP criteria for the Antimicrobial Preservative Effectiveness Test.

Signed: Eugene Aquisap, B.S. Microbiologist