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 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>
<thead>
<tr>
<th>Micro Organism</th>
<th>Initial Inoculum/gm</th>
<th>Colony forming units/ gm 14 days</th>
<th>Colony forming units/ gm 28 days</th>
<th>Log reduction 14 days</th>
<th>Log reduction 28 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. niger</td>
<td>4.8 x 10^5</td>
<td>&lt;10</td>
<td>&lt;10</td>
<td>4.7</td>
<td>4.7</td>
</tr>
<tr>
<td>B. albicans</td>
<td>3.2 x 10^5</td>
<td>&lt;10</td>
<td>&lt;10</td>
<td>4.5</td>
<td>4.5</td>
</tr>
<tr>
<td>E. coli</td>
<td>1.2 x 10^5</td>
<td>&lt;10</td>
<td>&lt;10</td>
<td>5.0</td>
<td>0.0</td>
</tr>
<tr>
<td>P. aeruginosa</td>
<td>6.7 x 10^5</td>
<td>&lt;10</td>
<td>&lt;10</td>
<td>4.8</td>
<td>0.0</td>
</tr>
<tr>
<td>S. aureus</td>
<td>7.3 x 10^5</td>
<td>&lt;10</td>
<td>&lt;10</td>
<td>4.9</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Table Summary

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 initial 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 initial 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