



MICROBIOLOGICAL REPORT

Simply Slick, LLC
 Attn: John Goepfert
 1621 N. Washington
 Jamesville, WI 53548

Report Date: 02/06/12
Date Received: 12/28/11
Date Completed: 01/31/12
Project #: 739864
P.O.#: SS12711
Reference #: 7314-089; 7289-163

Page 1 of 2

SAMPLE DESCRIPTION

| | | | | |
|---------------------------|---------------------------------|----------------------|------------------------|--------------------|
| <u>ACCESSION #</u> | <u>SAMPLE:</u> | <u>LOT #:</u> | <u>BATCH #:</u> | <u>QTY:</u> |
| 739864 | Simply Slick Lubricating Lotion | 10/2011 | Not Specified | 240mL (7) |

TEST PERFORMED:

| | | |
|-----------------------------------------------------------------------|----------------------------------------|-----------------------------------------------------------------|
| Validation Test for the Antimicrobial Preservative Effectiveness Test | <u>BTS METHOD #</u> M115.R10 | <u>REFERENCE:</u> United States Pharmacopeia 34, <51> |
| Antimicrobial Effectiveness Test (Category 2) | M101.R11 | United States Pharmacopeia 34, <51> |

PLATING MEDIA:

Microbial Content Test Agar (Bacteria)
 Sabouraud Dextrose Agar (Yeast and Mold)

ANTIMICROBIAL PRESERVATIVE EFFECTIVENESS VALIDATION TEST

| <u>Test Microorganism</u> | <u>Diluent</u> | <u>Dilution</u> | <u>Inoculum CFU/plate</u> | <u>Microbial Recovery CFU/plate</u> | <u>Percent Recovery</u> |
|----------------------------------|-----------------------|------------------------|--------------------------------------|------------------------------------------------|------------------------------------|
| <i>Aspergillus brasiliensis</i> | (mold) DNB | 1:10 | 23 | 11 | 48 |
| <i>Candida albicans</i> | (yeast) DNB | 1:10 | 39 | 37 | 95 |
| <i>Escherichia coli</i> | (bacteria) DNB | 1:10 | 40 | 42 | 105 |
| <i>Pseudomonas aeruginosa</i> | (bacteria) DNB | 1:10 | 17 | 16 | 94 |
| <i>Staphylococcus aureus</i> | (bacteria) DNB | 1:10 | 31 | 31 | 100 |

Re-tests:

The test was modified in an attempt to neutralize the antimicrobial properties in the sample to allow for growth of *Aspergillus brasiliensis*.

| <u>Test Microorganism</u> | <u>Diluent</u> | <u>Dilution</u> | <u>Inoculum CFU/plate</u> | <u>Microbial Recovery CFU/plate</u> | <u>Percent Recovery</u> |
|----------------------------------|-----------------------|------------------------|--------------------------------------|------------------------------------------------|------------------------------------|
| <i>Aspergillus brasiliensis</i> | DNB | 1:100 | 32 | 28 | 88 |
| <i>Aspergillus brasiliensis</i> | DNB | 1:1000 | 32 | 29 | 91 |

CFU = colony forming units

DNB = D/E Neutralizing Broth

CONCLUSION:

The antimicrobial preservative properties present in the sample can be neutralized under the test conditions described below:

| | <u>DILUENT</u> | <u>DILUTION</u> |
|---------------------------------|-----------------------|------------------------|
| <i>Aspergillus brasiliensis</i> | DNB | 1:100 |
| <i>Candida albicans</i> | DNB | 1:10 |
| <i>Escherichia coli</i> | DNB | 1:10 |
| <i>Pseudomonas aeruginosa</i> | DNB | 1:10 |
| <i>Staphylococcus aureus</i> | DNB | 1:10 |

ANTIMICROBIAL PRESERVATIVE EFFECTIVENESS TEST**RESULTS:****TABLE SUMMARY**

| <u>MICROORGANISM</u> | | <u>INITIAL INOCULUM/gm</u> | COLONY FORMING UNITS/gm | |
|---------------------------------|------------|---------------------------------------|--------------------------------|-----------------------|
| | | | <u>14 DAYS</u> | <u>28 DAYS</u> |
| <i>Aspergillus brasiliensis</i> | (mold) | 2.4E5 | 3.6E5 | 1.2E5 |
| <i>Candida albicans</i> | (yeast) | 1.6E5 | 50 | <10 |
| <i>Escherichia coli</i> | (bacteria) | 1.1E6 | 370 | <10 |
| <i>Pseudomonas aeruginosa</i> | (bacteria) | 7.3E5 | <10 | <10 |
| <i>Staphylococcus aureus</i> | (bacteria) | 9.3E5 | 10 | <10 |

Note: Numbers in the report such as 2.3E5 are an alternate exponential format for 2.3×10^5 .

LOG REDUCTION FROM INITIAL INOCULUM

| | <u>14 DAYS</u> | <u>28 DAYS</u> |
|---------------------------------|-----------------------|-----------------------|
| <i>Aspergillus brasiliensis</i> | -0.2 | 0.3 |
| <i>Candida albicans</i> | 3.5 | 4.2 |
| <i>Escherichia coli</i> | 3.5 | 5.0 |
| <i>Pseudomonas aeruginosa</i> | 4.9 | 4.9 |
| <i>Staphylococcus aureus</i> | 5.0 | 5.0 |

CONCLUSION:

The above test results meet the current USP Category 2 Criteria of Acceptance for the Antimicrobial Preservative Effectiveness Test.



Stephanie Hornby, M.S.

Microbiology Assistant Manager