



Micro Quality Labs

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BGP
2118 Wilshire Blvd. 766
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Submitted By: Allan Lord

Report Date: 5/6/08
Date Received: 4/25/08
Date Completed: 5/3/08
P.O. #:
Reference #: MQL# 1029905

SAMPLE DESCRIPTION:

ACCESSION

MQL# 1029905
#1152

SAMPLE

Biocence Mist

LOT

1077

TEST PERFORMED:

United States Pharmacopoeia
Effectiveness Testing

MQL METHOD

TM-03 Revision 5-24-03

METHOD REFERENCE#

USP 29-2006 Antimicrobial

RESULTS:

TABLE SUMMARY

Organism	Inoculum / g	Preservative Testing Colony Forming Units / gram		
		0 Hour Inoculum Control (Saline Solution)	0 Hour (less than 30 seconds)	2 Day
<i>Staphylococcus aureus</i> (bacteria) ATCC: 29213	2.50×10^6	6.8×10^5	<10	<10
<i>Pseudomonas aeruginosa</i> (bacteria) ATCC: 27853	1.77×10^6	9.6×10^5	<10	<10
<i>Pseudomonas aeruginosa</i> (bacteria) ATCC: 15442	1.7×10^6	9.6×10^5	<10	<10
<i>Escherichia coli</i> (bacteria) ATCC: 25922	1.30×10^6	6.2×10^4	<10	<10
<i>Pseudomonas putida</i> ATCC: 49128	1.5×10^6	1×10^5	<10	<10
<i>Pseudomonas stutzeri</i> ATCC: 17588	2.70×10^6	1×10^5	<10	<10
<i>Pseudomonas acnes</i> ATCC: 11827	1.0×10^6	9.8×10^5	<10	<10



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RESULTS:

TABLE SUMMARY

Organism	Inoculum / g	Preservative Testing Colony Forming Units / gram		
		0 Hour Inoculum Control (Saline Solution)	0 Hour (less than 30 seconds)	2 Day
<i>Methicillin Resistant Staphylococcus aureus (MRSA) ATCC: 33591</i>	2.0×10^6	6.2×10^4	<10	<10
<i>Staphylococcus epidermidis ATCC: 12228</i>	2.20×10^6	5.8×10^4	<10	<10
<i>Enterobacter cloacae ATCC: 13047</i>	1.50×10^6	9.1×10^5	<10	<10
<i>Enterococcus faecalis ATCC: 51299</i>	1.62×10^6	5.9×10^4	<10	<10
<i>Micrococcus luteus ATCC: 7468</i>	1.37×10^6	5.9×10^4	<10	<10
<i>Serratia marcescens ATCC: 14756</i>	1.70×10^6	9.8×10^5	<10	<10



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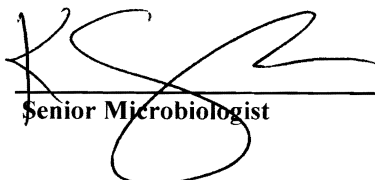
Interpretation for preservative testing

Cosmetic products are not expected to be aseptic; however, they must be completely free of high-virulence microbial pathogens, and the total number of aerobic microorganisms per gram must be low. Since there are not widely acceptable standards for numbers, temporary guidelines are used instead. For eye- area products, counts should not be greater than 500 colony forming units(CFU/g);for non-eye area products, counts should not be greater than 1000cfu/g. The presence of pathogens would be particularly important in evaluating as unacceptable a cosmetic with a marginally acceptable count, e.g.400 cfu/g for an eye-area product. Pathogens or opportunistic pathogens whose incidence would be of a particular concern in cosmetics would be *Staphylococcus aureus*, *Pseudomonas aeruginosa* and other species.

Cosmetic Preservative efficacy. The above guidelines for interpretation of results apply to cosmetic product before the time of use. Cosmetics contain antimicrobial preservatives and thus are expected to withstand a certain amount of abuse by users. Formerly, there were no validated tests for cosmetic preservative efficacy (3), although the test for pharmaceutical preservative efficacy in the U.S. Pharmacopoeia (2) or the cosmetic test in the technical guidelines of Cosmetic, Toiletry and Fragrance Association (CTFA)(1) were used. Recently, the CTFA test has been AOAC validated for use with liquid cosmetics. A test for solid cosmetic preservative efficacy has been proposed.(6). Cosmetics is reusable test kits such as those in retail stores, can be microbiologically evaluated semiquantitatively by a sterile swab test (5)

Preservative Challenge Results:

Based on the results, the preservative is effective in exerting its antimicrobial effectiveness.

 5/6/08 Germina Ratzung 5/6/08

Senior Microbiologist Date

References

- 1) Anonymous.1985. Preservation testing of aqueous liquid and semi-liquid eye cosmetics. In: CTFA Technical Guidelines. The Cosmetic, Toiletry and Fragrance Association,Inc.,
- 2) Anonymous. 1990. Antimicrobial preservatives-effectiveness. In: United States Pharmacopeia, 22nd Revision,p.1478. U.S. Pharmacopeial Convention, Rockville, MD.
- 3)Hitchins,A.D.1993 Cosmetic Preservation and safety:FDA Status.J.Assoc. Food Drug Official 57:42-49
- 4) Dunningan,A.P. 1968 Microbiological control of Cosmetics.Drug Cosmet. Ind.102:43-45,152-158
- 5)Tran,T.T.,A.D. Hitchins, and S.W. Collier.1990.Direct contact membrane method for evaluating preservative efficacy in solid cosmetics. Int.J. Cosmet.Sc. 12:175-183
- 6) Tran,T.T., A.D Hitchins.1194. Microbiological survey of shared-use cosmetic test kits available to the public, J. Ind. Microbial.13:389-391