



Micro Quality Labs

7421 Laurel Canyon #12 • North Hollywood, California 91605
 (818) 765-8176 • Fax: (818) 503-5464
 E-Mail: MicroQualityLabs@sbcglobal.net

BGP
 2118 Wilshire Blvd. 766
 Santa Monica, CA 90403
 Submitted By: Allan Lord

Report Date: 10/31/07
 Date Received: 10/6/07
 Date Completed: 10/31/07
 P.O. #:
 Reference #: MQL# 589905

SAMPLE DESCRIPTION:

ACCESSION #
 MQL# 589905
 #711

SAMPLE
 BIO911™

LOT #
 PA-08-032

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	Preservative Testing Colony Forming Units / gram						
	Inoculum / g	Day 0	Day 2	Day 7	Day 14	Day 21	Day 28
<i>Staphylococcus aureus</i> (bacteria) ATCC: 6538	2.50 x 10 ⁶	<10	<10	<10	<10	<10	<10
<i>Pseudomonas aeruginosa</i> (bacteria) ATCC: 9027	1.80 x 10 ⁶	<10	<10	<10	<10	<10	<10
<i>Escherichia coli</i> (bacteria) ATCC: 8739	2.00 x 10 ⁶	<10	<10	<10	<10	<10	<10
<i>Candida albicans</i> (yeast) ATCC: 10257	9.00 x 10 ⁴	<10	<10	<10	<10	<10	<10
<i>Asperigillus niger</i> (mold) ATCC: 16404	1.50 x 10 ⁵	<10	<10	<10	<10	<10	<10
<i>Pseudomonas putida</i> ATCC: 49128	1.80 x 10 ⁶	<10	<10	<10	<10	<10	<10
<i>Pseudomonas stutzeri</i> ATCC: 17588	1.80 x 10 ⁶	<10	<10	<10	<10	<10	<10
<i>Enterobacter cloacae</i> ATCC: 13047	2.00x10 ⁶	<10	<10	<10	<10	<10	<10
Methicillin Resistant <i>Staphylococcus aureus</i> (MRSA) ATCC: 33591	2.50x10 ⁶	<10	<10	NA	NA	NA	NA
Methicillin Resistant <i>Staphylococcus aureus</i> (duplicate MRSA) ATCC: 33591	2.50x10 ⁶	<10	<10	NA	NA	NA	NA



Micro Quality Labs
 7421 Laurel Canyon #12 • North Hollywood, California 91605
 (818) 765-8176 • Fax: (818) 503-5464
 E-Mail: MicroQualityLabs@sbcglobal.net

BGP
 2118 Wilshire Blvd. 766
 Santa Monica, CA 90403
 Submitted By: Allan Lord

Report Date: 10/31/07
 Date Received: 10/6/07
 Date Completed: 10/31/07
 P.O. #:
 Reference #: MQL# 589905

SAMPLE DESCRIPTION:

<u>ACCESSION #</u> MQL# 589905 #711	<u>SAMPLE</u> BIO911™	<u>LOT #</u> PA-08-032
--	---------------------------------	----------------------------------

<u>TEST PERFORMED:</u> United States Pharmacopoeia Effectiveness Testing	<u>MOQ METHOD #</u> TM-03 Revision 5-24-03	<u>METHOD REFERENCE#</u> USP 29-2006 Antimicrobial
---	--	--

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

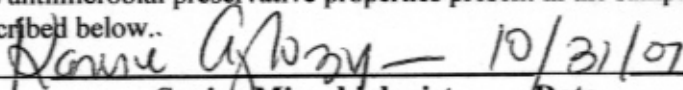
RESULTS:

Preservative Testing Validation					
Organism	Inoculum	Dilution	Microbial Recovery	Diluent	Percent Recovery
<i>Staphylococcus aureus</i>	82cfu/plate	1:10	81cfu/plate	LB	<u>99%</u>
<i>Pseudomonas aeruginosa</i>	75cfu/plate	1:10	69cfu/plate	LB	<u>92%</u>
<i>Escherichia coli</i>	85cfu/plate	1:10	79cfu/plate	LB	<u>93%</u>
<i>Candida albicans</i>	28cfu/plate	1:10	23cfu/gm	LB	<u>82%</u>
<i>Asperigillus niger</i>	34cfu/plate	1:10	27cfu/gm	LB	<u>79%</u>
<i>Pseudomonas putida</i>	75cfu/plate	1:10	69cfu/plate	LB	<u>92%</u>
<i>Pseudomonas stutzeri</i>	75cfu/plate	1:10	69cfu/plate	LB	<u>92%</u>
<i>Enterobacter cloacae</i>	85cfu/plate	1:10	79cfu/plate	LB	<u>93%</u>

CFU = colony forming units LB = Lethen Broth
 Diluent: Leetheen broth Dilution: 1:10

CONCLUSION:

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



 Senior Microbiologist Date



7421 Laurel Canyon #12 • North Hollywood, California 91605

(818) 765-8176 • Fax: (818) 503-5464

E-Mail: MicroQualityLabs@sbcglobal.net

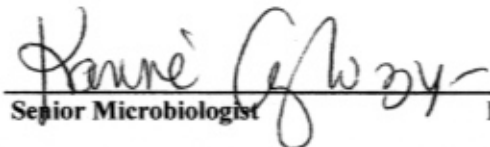
Interpretation for preservative testing

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. The preservative is effective in maintaining the sterility of the product.

 Laurie Conway
Senior Microbiologist

 10/31/07
Date





Micro Quality Labs
 7421 Laurel Canyon #12 • North Hollywood, California 91605
 (818) 765-8176 • Fax: (818) 503-5464
 E-Mail: MicroQualityLabs@sbcglobal.net

BGP
 2118 Wilshire Blvd. 766
 Santa Monica, CA 90403
 Submitted By: Allan Lord

Report Date: 06/09/09
 Date Received: 05/05/09
 Date Completed: 06/05/09
 P.O. #:
 Reference #: 1805

SAMPLE DESCRIPTION:

<u>ACCESSION #</u>	<u>SAMPLE</u>	<u>LOT #</u>
MQL# 1805	Biotanic OTC Surface Spray Alcohol Free	N/A

<u>TEST PERFORMED:</u>	<u>SQL METHOD #</u>	<u>METHOD REFERENCE#</u>
United States Pharmacopoeia	TM-03	USP 32-2009 Antimicrobial Effectiveness Testing

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

RESULTS:

Preservative Testing Validation					
Organism	Inoculum	Dilution	Microbial Recovery	Diluent	Percent Recovery
<i>Staphylococcus pneumoniae</i> (bacteria) ATCC: 700677	35cfu/plate	1:10	31cfu/plate	LB	<u>89%</u>
<i>Staphylococcus epidermidis</i> ATCC: 12228	50fu/plate	1:10	43cfu/plate	LB	<u>86%</u>
<i>Staphylococcus haemolyticus</i> ATCC: 29970	75cfu/plate	1:10	69cfu/plate	LB	<u>92%</u>
<i>Staphylococcus saprophyticus</i> ATCC: 43867	93cfu/plate	1:10	82cfu/gm	LB	<u>88%</u>
<i>Staphylococcus aureus</i> ATCC: 29213	83cfu/plate	1:10	81cfu/gm	LB	<u>98%</u>
<i>Escherichia coli</i> (bacteria) ATCC: 25922	75cfu/plate	1:10	72cfu/plate	LB	<u>96%</u>
<i>Escherichia coli</i> (bacteria) ATCC: 11229	51cfu/plate	1:10	42cfu/plate	LB	<u>82%</u>
<i>Pseudomonas aeruginosa</i> (bacteria) ATCC: 27853	78cfu/plate	1:10	73cfu/plate	LB	<u>94%</u>
<i>Pseudomonas aeruginosa</i> (bacteria) ATCC: 15442	63cfu/plate	1:10	59cfu/plate	LB	<u>94%</u>
<i>Pseudomonas putida</i> ATCC: 49128	42cfu/plate	1:10	40cfu/plate	LB	<u>95%</u>



Micro Quality Labs

7421 Laurel Canyon #12 • North Hollywood, California 91605

(818) 765-8176 • Fax: (818) 503-5464

E-Mail: MicroQualityLabs@sbcglobal.net

BGP
2118 Wilshire Blvd. 766
Santa Monica, CA 90403
Submitted By: Allan Lord

Report Date: 06/09/09
Date Received: 05/05/09
Date Completed: 06/05/09
P.O. #:
Reference #: 1805

SAMPLE DESCRIPTION:

<u>ACCESSION #</u>	<u>SAMPLE</u>	<u>LOT #</u>
MQL# 1805	Biotanic OTC Surface Spray Alcohol Free	N/A

<u>TEST PERFORMED:</u>	<u>MLQ METHOD #</u>	<u>METHOD REFERENCE#</u>
United States Pharmacopoeia	TM-03	USP 32-2009 Antimicrobial Effectiveness Testing

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

RESULTS:

Organism	Preservative Testing Validation				
	Inoculum	Dilution	Microbial Recovery	Diluent	Percent Recovery
<i>Pseudomonas stutzeri</i> ATCC: 17588	96cfu/plate	1:10	92cfu/plate	LB	<u>96%</u>
<i>Pseudomonas fluorescens</i> ATCC: 13525	83cfu/plate	1:10	79cfu/plate	LB	<u>95%</u>
<i>Enterobacter cloacae</i> ATCC: 13047	64cfu/plate	1:10	64cfu/plate	LB	<u>100%</u>
<i>Proteus mirabilis</i> ATCC: 12453	69cfu/plate	1:10	67cfu/plate	LB	<u>97%</u>
<i>Micrococcus luteus</i> ATCC: 7468	97cfu/plate	1:10	92cfu/plate	LB	<u>95%</u>
<i>Enterococcus Faecalis</i> ATCC: 51299	62cfu/plate	1:10	60cfu/gm	LB	<u>97%</u>
<i>Klebsiella Pheymoniae</i> ATCC: 13882	27cfu/plate	1:10	27cfu/gm	LB	<u>100%</u>
<i>Klebsiella Pheumoniae</i> ATCC: 10031	93cfu/plate	1:10	88cfu/plate	LB	<u>95%</u>
<i>Serratia Mazcescens</i> ATCC: 14756	98cfu/plate	1:10	92cfu/plate	LB	<u>94%</u>
<i>Haemophilus influenzae</i> ATCC: 19418	37cfu/plate	1:10	29cfu/plate	LB	<u>78%</u>

CFU = colony forming units LB = Leethen Broth
Diluent: Leethen broth Dilution: 1:10

CONCLUSION:

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

Samir G. Wazny - 6/9/09
Senior Microbiologist Date



7421 Laurel Canyon #12 • North Hollywood, California 91605

(818) 765-8176 • Fax: (818) 503-5464

E-Mail: MicroQualityLabs@sbcglobal.net


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 1000 cfu/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. The preservative is effective in maintaining the sterility of the product.



Senior Microbiologist 6/9/09
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



Micro Quality Labs

7421 Laurel Canyon #12 • North Hollywood, California 91605

(818) 765-8176 • Fax: (818) 503-5464

E-Mail: MicroQualityLabs@sbcglobal.net

MICROBIOLOGICAL REPORT

BGP LLC

Attn: Allan Lord

2118 Wilshire Blvd. # 766

Santa Monica, CA 90403

Report Date: 11/14/07

Date Received: 12/03/07

Date Completed: 12/03/07

Project #: 794

P.O. #: Not Specified

Reference #: 794

SAMPLE DESCRIPTION:

<u>ACCESSION #</u>	<u>SAMPLE:</u>	<u>LOT #</u>	<u>BATCH#</u>	<u>QTY.</u>
Project #794	TAN Liquid	10.30.07	PA -08-032	20 pounds

TEST PERFORMED:

Bacterial Reduction –

Reference AOAC

The log reduction is used to determine the effectiveness of a product at reducing a specific microorganism population.

Methicillin Resistant Staphylococcus aureus (MRSA) was prepared by inoculating the surface of TSA slants. Each microorganism was then incubated at 30 to 35°C for 18 to 24 hours. Following the incubation period the slants were washed with sterile Serological Saline Solution to harvest the microorganisms. Using Culti-Loops microorganisms were grown and adjusted to 10^8 (cfu) colony forming units per mL and used as a stock suspension. An additional 1:10 dilution of the stock suspension was made using Serological Saline Solution to achieve a concentration of approximately 10^7 CFU per mL.

For the microorganism to be tested, 20 mL of test product and 20 mL of Serological Saline Solution was added into separate sterile tubes. Each 20mL sample of test product and Serological Saline Solution was inoculated with 0.2 mL of the 10^7 CFU/mL suspensions. These inoculums resulted in approximately 10^6 CFU.mL into the product and Serological Saline Solution control.

At the time intervals of 30 seconds, 60 seconds, 120 seconds, 180 seconds, and 1 hour, 1.0 mL from the inoculated test product was taken and placed into 9.0 mL of Modified Lethen Broth (1:10 Dilution). Additional 1:10 serial dilutions were prepared using neutralizing broth to achieve 1:100 and 1:1000 dilutions.

1 mL from each dilution was plated in sterile Petri dishes and melted TSA agar was added as the growth medium for bacterial organisms.

The bacterial plates were incubated at 30 to 35°C for 48 hours. The same procedure was repeated for the Serological Saline Solution control. After the incubation period, all plates were counted to determine the number of microorganisms remaining at the various time points



Micro Quality Labs

7421 Laurel Canyon #15 • North Hollywood, California 91605

(818) 765-8176 • Fax: (818) 503-5464

E-Mail: MicroQualityLabs@sbcglobal.net

BGP LLC

Project # 794

Page 2 of 2

RESULTS:

Methicillin Resistant Staphylococcus aureus (MRSA)

ATCC 33591

EXPOSURE TIME	CONCENTRATION OF ORGANISM (CFU/mL)		% REDUCTION		LOG REDUCTION	
	CONTROL	PRODUCT	CONTROL	PRODUCT	CONTROL	PRODUCT
INITIAL	2.0 x 10 ⁶					N/A
30 sec.	1.80 x 10 ⁶	1:10 dilution <10	N/A	100%	0.05	N/A
1 min.	5.0 x 10 ⁵	1:10 dilution <10	75%	100%	0.60	N/A
2 min.	5.0 x 10 ⁵	1:10 dilution <10	75%	100%	0.60	N/A
3 min.	5.6 x 10 ⁵	1:10 dilution <10	72%	100%	0.60	N/A
1 hour	2.66x10 ⁵	1:10 dilution <10	87%	100%	0.88	N/A

Data Calculation:

The concentration of each microorganism for the control and product is listed for each interval. These numbers are expressed in terms of scientific notation. The next two headings represent the “% reduction” and “Log Reduction” information for each time point. Both calculations are used to express the change (reduction or increase) of the microorganism population relative to starting inoculums.

$$\% \text{ Reduction} = \frac{\text{Initial Count} - \text{Count at x time interval}}{\text{Initial Count}} \times 100$$

For Example: % Reduction For *MRSA* at 30 seconds for test product

$$\frac{2.0 \times 10^6 - 1.8 \times 10^6}{2.0 \times 10^6}$$

The log reduction is calculated as follows:

$$\text{Log}_{10}(\text{initial count}) - \text{Log}_{10}(\text{x times interval}) = \text{Log reduction}$$

For example: $\text{Log}(2.0 \times 10^6 \text{ CFU/gm}) - \text{Log}_{10}(1.8 \times 10^6 \text{ CFU/gm}) = 6.3 - 6.25 = 0.05 \text{ reduction}$

Discussion:

The minimum bactericidal concentration is defined as 99.9% decrease (3 log) in the initial inoculums. The test product had no counts for growth when exposed to *Methicillin Resistant Staphylococcus aureus (MRSA)* at all time intervals.

Conclusion:

The results indicate that BGP has antimicrobial activity against *Methicillin Resistant Staphylococcus aureus (MRSA)*, Culti-Loop, ATCC # 33591 at 30 seconds contact time. The aforementioned results on this report are representative of the samples submitted and may not be indicative of the entire manufacture, batch, and/or lot. Applicable current GMP's shall always be used when sampling. GLP's shall always be practiced by Micro Quality Labs to ensure the most accurate results.

Approved:

Karine Aylozyan....Senior Microbiologist/Q.A. Coordinator Germina Ratquaz Senior Microbiologist

K- 8037-

Ratquaz 1/14/07

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



NON-GLP STUDY REPORT

STUDY TITLE

Time Kill Assay For Antimicrobial Agents

Test Organism:

Community Acquired Methicillin Resistant *Staphylococcus aureus* - CA-MRSA
Genotype USA 300 (NARSA NRS 384)

PRODUCT IDENTITY

Biocence W.S. Liquid, Botanical Human OTC Drug
(NDC# 59998)

AUTHOR

Jamie Herzan, B.S.
Senior Microbiologist

STUDY COMPLETION DATE

September 26, 2017

PERFORMING LABORATORY

Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

SPONSOR

Anti-Microbial Technology, Inc.
40575 Cal Oaks Rd., D2, #238
Murrieta, CA 92562-5856

PROJECT NUMBER

A23991

This study was not performed under U.S. EPA 40 CFR
Part 160 or U.S. FDA 21 CFR Part 58

Page 1 of 6

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Time Kill Assay For Antimicrobial Agents
Project Number: A23991
Protocol Number: ANT002082417.TK.2

TEST SUBSTANCE IDENTITY

Test Substance Name: Biocence W.S. Liquid, Botanical Human OTC Drug (NDC# 59998)

STUDY DATES

Date Sample Received: September 11, 2017
Study Initiation Date: September 12, 2017
Experimental Start Date: September 19, 2017
Experimental End Date: September 21, 2017
Study Completion Date: September 26, 2017

Test Organism	Designation #	Growth Medium	Incubation Parameters
Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> - CA-MRSA Genotype USA 300	NRS 384	Tryptic Soy Agar + 5% Sheep's Blood	35-37°C, aerobic

The test organism used in this study was obtained from the NARSA Contracts Administrator at Focus Technologies, Inc., Herndon, VA 20171.

Test Substance Dilution: 4 cc/10 cc defined as 4 cc of test substance + 6 cc of autoclave sterilized deionized water
Exposure Times: 1 minute, 3 minutes and 5 minutes
Exposure Temperature: Ambient temperature (20°C)
Number of Replicate/Sample: 1 replicate per batch
Soil Load Description: 5% Fetal Bovine Serum
Neutralizer: D/E Neutralizing Broth
Agar Plate Medium: Tryptic Soy Agar + 5% Sheep Blood

EXPERIMENTAL DESIGN

A suspension of the test organism was exposed to the test substance for the specified exposure times. After exposure, an aliquot of the suspension was transferred to neutralizer and was assayed for survivors. Appropriate culture purity, organic soil load sterility, neutralizer sterility, test population and neutralization confirmation controls were performed.

Per Sponsor's direction, the study was not required to be conducted under U.S. EPA 40 CFR Part 160 or U.S. FDA 21 CFR Part 58.

STUDY RESULTS

TABLE 1: CONTROL RESULTS

The following results from controls confirmed study validity:

Type of Control		Results
Purity Control	Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> - CA-MRSA Genotype USA 300 (NARSA NRS 384)	Pure
Organic Soil Load Sterility Control		No Growth
Neutralizer Sterility Control		No Growth

TABLE 2: TEST POPULATION CONTROL RESULTS

Test Organism	Results	
	CFU/mL	Log ₁₀
Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> - CA-MRSA Genotype USA 300 (NARSA NRS 384)	3.8 x 10 ⁶	6.58

CFU = Colony Forming Units

TABLE 3: NEUTRALIZATION CONFIRMATION CONTROL RESULTS

Test Substance	Test Organism	Neutralization Confirmation (CFU)		Pass/Fail (Log ₁₀ Difference)
		Numbers Control	Test Substance Results	
Biocence W.S. Liquid, Botanical Human OTC Drug (NDC# 59998)	Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> - CA-MRSA Genotype USA 300 (NARSA NRS 384)	74, 73	74, 74	Pass (0.00)

CFU = Colony Forming Units

TABLE 4: TEST RESULTS FOR Biocence W.S. Liquid, Botanical Human OTC Drug (NDC# 59998)

DILUTION (VOLUME PLATED)	Test Organism: Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> - CA-MRSA Genotype USA 300 (NARSA NRS 384)		
	Exposure Time		
	1 minute	3 minute	5 minutes
	Number of Survivors		
10 ⁰ (1.00 mL)	T, T	T, T	T, T
10 ⁰ (0.100 mL)	T, T	140, 202	152, 162
10 ⁻¹ (0.100 mL)	27, 34	18, 22	17, 15
10 ⁻² (0.100 mL)	2, 3	0, 3	0, 0
10 ⁻³ (0.100 mL)	0, 0	0, 1	0, 0

T = Too Numerous To Count (>300 colonies)

TABLE 5: CALCULATED DATA FOR Biocence W.S. Liquid, Botanical Human OTC Drug (NDC# 59998)

Test Organism: Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> – CA-MRSA Genotype USA 300 (NARSA NRS 384)					
Exposure Time	CFU/mL in Test Population Control (Log₁₀)	CFU/mL of Survivors	Log₁₀ Survivors	Percent Reduction	Log₁₀ Reduction
1 minute	3.8 x 10 ⁶ (6.58)	3.1 x 10 ⁴	4.49	99.2%	2.09
3 minutes		1.71 x 10 ⁴	4.23	99.6%	2.35
5 minutes		1.57 x 10 ⁴	4.20	99.6%	2.38

CFU = Colony Forming Units

TABLE 6: VERIFICATION OF ANTIBIOTIC RESISTANCE

Quality Control Organism	Zone of Inhibition (mm)	CLSI* Acceptable Range (mm)
<i>Staphylococcus aureus</i> (ATCC 25923)	18	18 – 24
Test Organism	Zone of Inhibition (mm)	CLSI* Resistant Range (mm)
Community Acquired Methicillin Resistant <i>Staphylococcus aureus</i> - CA-MRSA Genotype USA 300 (NARSA NRS 384)	6	≤10

*CLSI = Clinical and Laboratory Standards Institute
 Interpretation of result and acceptable range are from the Clinical and Laboratory Standards Institute, Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Second Information Supplement January 2012, Volume 31 Number 1, Approved Standard M02-A11 and M07-A9, Wayne, Pennsylvania.

CONTROL RESULTS

All controls including culture purity, organic soil load sterility, neutralizer sterility, test population and neutralization confirmation were all acceptable.

**ANALYSIS**

Biocence W.S. Liquid, Botanical Human OTC Drug (NDC# 59998) diluted 4 cc/10 cc defined as 4 cc of test substance + 6 cc of sterile deionized water, demonstrated a 99.2% (2.09 log₁₀) reduction of Community Acquired Methicillin Resistant *Staphylococcus aureus* - CA-MRSA Genotype USA 300 (NARSA NRS 384) survivors following a 1 minute exposure time, a 99.6% (2.35 log₁₀) reduction of Community Acquired Methicillin Resistant *Staphylococcus aureus* - CA-MRSA Genotype USA 300 (NARSA NRS 384) survivors after a 3 minute exposure time and a 99.6% (2.38 log₁₀) reduction of Community Acquired Methicillin Resistant *Staphylococcus aureus* - CA-MRSA Genotype USA 300 (NARSA NRS 384) survivors after a, 5 minute exposure when tested at ambient temperature (20°C) in the presence of a 5% fetal bovine serum organic soil load.

PREPARED BY:

Jamie Herzan, B.S.
Senior Microbiologist

9-26-17
Date

The use of the Accuratus Lab Services name, logo or any other representation of Accuratus Lab Services without the written approval of Accuratus Lab Services is prohibited. In addition, Accuratus Lab Services may not be referred to in any form of promotional materials, press releases, advertising or similar materials (whether by print, broadcast, communication or electronic means) without the expressed written permission of Accuratus Lab Services.