

**BIO SCIENCE**  
LABORATORIES • INC

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December 7, 2005

FINAL REPORT #050812-201

**AN EVALUATION OF ONE (1) TEST PRODUCT (MICROCYN™)  
AND TWO (2) REFERENCE PRODUCTS (HIBICLENS® AND PLACEBO SOLUTION) FOR THEIR  
ANTIMICROBIAL PROPERTIES WHEN CHALLENGED WITH VARIOUS MICROORGANISM  
STRAINS USING AN IN-VITRO TIME-KILL METHOD**

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## EXECUTIVE SUMMARY

An In-Vitro Time-Kill evaluation was performed using one (1) test product and two (2) reference products. The test product (Microcyn™) was evaluated versus challenge suspensions of fifty (50) different microorganism strains -- twenty-five (25) American Type Culture Collection (ATCC) strains and twenty-five (25) Clinical Isolates of those same species, as described in the Tentative Final Monograph, *Federal Register*, 17 June 1994, vol. 59:116, p. 31444. Each reference product (HIBICLENS® Chlorhexidine Gluconate solution 4.0% [w/v] and 0.9% Sodium Chloride Irrigation, USP) was evaluated versus suspensions of the ten (10) American Type Culture Collection (ATCC) strains specifically denoted in the Tentative Final Monograph. The percent reductions and the Log<sub>10</sub> reductions from the initial population of each challenge strain were determined following exposures to the products for thirty (30) seconds, one (1) minute, three (3) minutes, five (5) minutes, seven (7) minutes, nine (9) minutes, eleven (11) minutes, thirteen (13) minutes, fifteen (15) minutes, and twenty (20) minutes. The test product and the reference products each were evaluated at a 99% (v/v) concentration.

Product #1, Microcyn™ (Lot Number RDH103105-02), demonstrated rapid antimicrobial activity versus a broad spectrum of challenge microorganisms. Microbial populations of forty-seven (47) of the fifty (50) Gram-positive, Gram-negative, and yeast species evaluated were reduced by more than 5.0 Log<sub>10</sub> within thirty (30) seconds of exposure to the product. A thirty (30) second exposure to Microcyn™ reduced the population of *Streptococcus pneumoniae* (Clinical Isolate; BSLI #072605Spn1) by more than 4.5 Log<sub>10</sub>, which was the limit of detection versus this species. When challenged with *Candida tropicalis* (ATCC #750 and Clinical Isolate [BSLI #042905Ct]), Product #1 demonstrated a slightly reduced rate of antimicrobial activity. Microbial reductions in excess of 3.0 Log<sub>10</sub> were achieved versus *Candida tropicalis* (ATCC #750) following a thirty (30) second exposure, and versus *Candida tropicalis* (BSLI #042905Ct), following a twenty (20) minute exposure.

Product #2, HIBICLENS® Chlorhexidine Gluconate solution 4.0% (w/v) (Lot Number 505733), reduced microbial populations of six (6) challenge strains by more than 5.0 Log<sub>10</sub> following thirty (30) second exposures: *Escherichia coli* (ATCC #11229 and ATCC #25922), *Pseudomonas aeruginosa* (ATCC #15442 and ATCC #27853), *Serratia marcescens* (ATCC #14756), and *Staphylococcus epidermidis* (ATCC #12228). A thirty (30) second exposure to HIBICLENS® reduced the population of *Micrococcus luteus* (ATCC #7468) by more than 4.8 Log<sub>10</sub>, which was the limit of detection versus this species. Microbial reductions in excess of 5.0 Log<sub>10</sub> were produced by Product #2 versus *Enterococcus faecalis* (ATCC #29212) following a three (3) minute exposure, and versus *Staphylococcus aureus* (ATCC #6538 and ATCC #29213) following five (5) minute exposures.

Product #3, Sterile 0.9% Sodium Chloride Irrigation, USP (Lot Number G029462), reduced microbial populations of each of the ten (10) challenge strains by less than 0.3 Log<sub>10</sub> following twenty (20) minute exposures.

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1.0 **TITLE:** AN EVALUATION OF ONE (1) TEST PRODUCT (MICROCYN™) AND TWO (2) REFERENCE PRODUCTS (HIBICLENS® AND PLACEBO SOLUTION) FOR THEIR ANTIMICROBIAL PROPERTIES WHEN CHALLENGED WITH VARIOUS MICROORGANISM STRAINS USING AN IN-VITRO TIME-KILL METHOD

2.0 **SPONSOR:** OCULUS INNOVATIVE SCIENCES  
1129 N. McDowell Boulevard  
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3.0 **COMPANY:** BIOSCIENCE LABORATORIES, INC.  
300 N. Willson Avenue  
Bozeman, Montana 59715

4.0 **STUDY DIRECTORS:**

Terri Eastman - Principal Study Director  
Jessica McDonnell - Associate Study Director

5.0 **PURPOSE OF STUDY:**

This evaluation used an In-Vitro Time-Kill Method to assess the broad-spectrum antimicrobial efficacy of one (1) test product (Microcyn™) and two (2) reference products (HIBICLENS® Chlorhexidine Gluconate solution 4.0% [w/v] and 0.9% Sodium Chloride Irrigation, USP) when challenged with various microorganism strains. The test product and the reference products each were evaluated at a 99% (v/v) concentration. All testing was performed in accordance with Good Laboratory Practices, as specified in 21 CFR Part 58.

6.0 **SCOPE:**

An In-Vitro Time-Kill evaluation was performed using one (1) test product and two (2) reference products. The test product (Microcyn™) was evaluated versus challenge suspensions of fifty (50) different microorganism strains -- twenty-five (25) American Type Culture Collection (ATCC) strains and twenty-five (25) Clinical Isolates of those same species, as described in the Tentative Final Monograph, *Federal Register*, 17 June 1994, vol. 59:116, p. 31444. Each reference product (HIBICLENS® Chlorhexidine Gluconate solution 4.0% [w/v] and 0.9% Sodium Chloride Irrigation, USP) was evaluated versus suspensions of the ten (10) American Type Culture Collection (ATCC) strains specifically denoted in the Tentative Final Monograph. The percent reductions and the Log<sub>10</sub> reductions from the initial population of each challenge strain were determined following exposures to the products for thirty (30) seconds, one (1) minute, three (3) minutes, five (5) minutes, seven (7) minutes, nine (9) minutes, eleven (11) minutes, thirteen (13) minutes, fifteen (15) minutes, and twenty (20) minutes. All agar-plating was performed in duplicate. The Study Protocol, included in Addendum I of this Final Report, presents the study methodology in detail, as do General Data Gathering Forms (Form No. 91-L-002) in Addendum VI of this Final Report. The Study Protocol was amended once to clarify that BioScience Laboratories, Inc. would be responsible for providing the Placebo Solution -- 0.9% Sodium Chloride Irrigation, USP (Reference Product) (reference Protocol Amendment Form [Form No. 94-G-006] in Addendum I of this Final Report). No deviations from the methodology described in the Study Protocol occurred during the course of this evaluation.

## 7.0 TEST MATERIALS:

The test product (Microcyn™) and one (1) of the reference products (HIBICLENS® Chlorhexidine Gluconate solution 4.0% [w/v]) were provided to Company by Sponsor. Company provided the Placebo Solution -- 0.9% Sodium Chloride Irrigation, USP (Reference Product). Responsibility for the identity, strength, purity, composition, stability, and retention of all test materials remained with Sponsor.

Product #1: Test Product (Microcyn™)  
Lot Number: RDH103105-02  
Expiration Date: 2006-10

Product #2: Reference Product (HIBICLENS® Chlorhexidine Gluconate solution 4.0% [w/v] [Active Control])  
Manufacturer: Regent Medical  
Lot Number: 505733  
Expiration Date: 06/2007

Product #3: Reference Product (Sterile 0.9% Sodium Chloride Irrigation, USP [Placebo Solution])  
Manufacturer: Baxter Healthcare Corp.  
Lot Number: G029462  
Expiration Date: JUN 07

## 8.0 CHALLENGE MICROORGANISMS :

The challenge microorganisms (American Type Culture Collection [ATCC] and Clinical Isolate Strains) evaluated are described below:

- 8.1 *Acinetobacter baumannii* (ATCC #19003)
- 8.2 *Acinetobacter baumannii* (Clinical Isolate; BSLI #061901Ab3)
- 8.3 *Bacteroides fragilis* (ATCC #43858)
- 8.4 *Bacteroides fragilis* (Clinical Isolate; BSLI #061901Bf6)
- 8.5 *Candida albicans* (ATCC #10231)
- 8.6 *Candida albicans* (Clinical Isolate; BSLI #042905Ca)
- 8.7 *Candida tropicalis* (ATCC #750)
- 8.8 *Candida tropicalis* (Clinical Isolate; BSLI #042905Ct)
- 8.9 *Enterobacter aerogenes* (ATCC #29007)
- 8.10 *Enterobacter aeruginosa* (Clinical Isolate; BSLI #042905Ea)
- 8.11 *Enterococcus faecalis* (ATCC #29212) \*
- 8.12 *Enterococcus faecalis* (Clinical Isolate; BSLI #061901Efs2)
- 8.13 *Enterococcus faecium* VRE, MDR (ATCC #51559)
- 8.14 *Enterococcus faecium* (Clinical Isolate; BSLI #061901Efm1)
- 8.15 *Escherichia coli* (ATCC #11229) \*
- 8.16 *Escherichia coli* (Clinical Isolate; BSLI #042905Ec1)
- 8.17 *Escherichia coli* (ATCC #25922) \*
- 8.18 *Escherichia coli* (Clinical Isolate; BSLI #042905Ec2)
- 8.19 *Haemophilus influenzae* (ATCC #8149)
- 8.20 *Haemophilus influenzae* (Clinical Isolate; BSLI #072605Hi)
- 8.21 *Klebsiella oxytoca* MDR (ATCC #15764)
- 8.22 *Klebsiella oxytoca* (Clinical Isolate; BSLI #061901Ko1)
- 8.23 *Klebsiella pneumoniae* subsp. *ozaenae* (ATCC #29019)
- 8.24 *Klebsiella pneumoniae* (Clinical Isolate; BSLI #061901Kpn2)

VRE = Vancomycin-Resistant *Enterococcus*

MDR = Multi-Drug Resistant

\* = Challenge strain evaluated against Products #1, #2, and #3. All other strains evaluated versus Product #1, only.

- 8.25 *Micrococcus luteus* (ATCC #7468) \*
  - 8.26 *Micrococcus luteus* (Clinical Isolate; BSLI #061901M12)
  - 8.27 *Proteus mirabilis* (ATCC #7002)
  - 8.28 *Proteus mirabilis* (Clinical Isolate; BSLI #061901Pm2)
  - 8.29 *Pseudomonas aeruginosa* (ATCC #15442) \*
  - 8.30 *Pseudomonas aeruginosa* (Clinical Isolate; BSLI #072605Pa)
  - 8.31 *Pseudomonas aeruginosa* (ATCC #27853) \*
  - 8.32 *Pseudomonas aeruginosa* (Clinical Isolate; BSLI #061901Pa2)
  - 8.33 *Serratia marcescens* (ATCC #14756) \*
  - 8.34 *Serratia marcescens* (Clinical Isolate; BSLI #042905Sm)
  - 8.35 *Staphylococcus aureus* (ATCC #6538) \*
  - 8.36 *Staphylococcus aureus* (Clinical Isolate; BSLI #061901Sa1)
  - 8.37 *Staphylococcus aureus* (ATCC #29213) \*
  - 8.38 *Staphylococcus aureus* (Clinical Isolate; BSLI #061901Sa2)
  - 8.39 *Staphylococcus epidermidis* (ATCC #12228) \*
  - 8.40 *Staphylococcus epidermidis* (Clinical Isolate; BSLI #072605Se)
  - 8.41 *Staphylococcus haemolyticus* (ATCC #29970)
  - 8.42 *Staphylococcus haemolyticus* (Clinical Isolate; BSLI #042905Sha)
  - 8.43 *Staphylococcus hominis* (ATCC #27844)
  - 8.44 *Staphylococcus hominis* (Clinical Isolate; BSLI #042905Sho)
  - 8.45 *Staphylococcus saprophyticus* (ATCC #35552)
  - 8.46 *Staphylococcus saprophyticus* (Clinical Isolate; BSLI #042905Ss)
  - 8.47 *Streptococcus pneumoniae* (ATCC #33400)
  - 8.48 *Streptococcus pneumoniae* (Clinical Isolate; BSLI #072605Spn1)
  - 8.49 *Streptococcus pyogenes* (ATCC #19615)
  - 8.50 *Streptococcus pyogenes* (Clinical Isolate; BSLI #061901Spy7)
- \* = Challenge strain evaluated against Products #1, #2, and #3. All other strains evaluated versus Product #1, only.

## 9.0 EQUIPMENT AND SUPPLIES:

The equipment and supplies used in this study are as described in the Study Protocol in Addendum I of this Final Report. Additional details are recorded on Equipment Tracking Forms (Form No. 98-L-007) in Addendum VIII of this Final Report.

## 10.0 MEDIA:

The growth media and diluting fluids used in this study are as described in the Study Protocol in Addendum I of this Final Report. Additional details are recorded on Media/Diluent Tracking Forms (Form No. 97-L-007) in Addendum V of this Final Report.

## 11.0 NEUTRALIZATION STUDY:

- 11.1 Neutralization studies (SOP L-2007) were performed for the test product versus *Bacteroides fragilis* (ATCC #43858), *Escherichia coli* (ATCC #11229), and *Streptococcus pneumoniae* (ATCC #33400), and for the reference products versus *Escherichia coli* (ATCC #11229) and *Staphylococcus aureus* (ATCC #6538), to ensure that the neutralizing solution employed (BBP++) was effective in neutralizing the antimicrobial properties of the test and reference products. This neutralization procedure followed guidelines set forth in ASTM E 1054-02, *Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents*, except that the challenge microorganisms were added to the neutralizing solution prior to the addition of the test or reference products. This neutralization procedure demonstrated effective neutralization of the antimicrobial activity of the test and reference products, as described below. All data resulting from the Neutralization Assay are included in Addendum IV of this Final Report.

- 11.2 When challenged with *Bacteroides fragilis* (ATCC #43858) and *Escherichia coli* (ATCC #11229), the antimicrobial properties of Product #1 (reference Section 7.0) were effectively neutralized at all dilutions plated. When challenged with *Streptococcus pneumoniae* (ATCC #33400), the neutralizing solution (BBP++) alone, and in combination with Product #1 at a 1:10 (v/v) dilution, produced colonies of reduced size and number -- an indication of possible inhibitory activity at this dilution. At higher dilutions (i.e., 1:100, 1:1,000, 1:10,000, etc.), this inhibitory activity was not observed. Hence, for *Streptococcus pneumoniae* (ATCC #33400 and Clinical Isolate), and *Haemophilus influenzae* (ATCC #8149 and Clinical Isolate), counts from the 10<sup>-3</sup> dilution plated subsequent to Time-Kill exposures were considered to be unreliable and were not used for calculations of post-exposure populations.
- 11.3 When challenged with *Escherichia coli* (ATCC #11229), the antimicrobial properties of Product #2 (reference Section 7.0) were effectively neutralized at all dilutions plated. When challenged with *Staphylococcus aureus* (ATCC #6538), the neutralizing solution, in combination with Product #2 at a 1:10 (v/v) dilution, produced colonies of reduced size and number -- an indication of possible inhibitory activity at this dilution. At higher dilutions (i.e., 1:100 and 1:1,000 product dilutions), this inhibitory activity was not observed. Hence, for *Staphylococcus aureus* (ATCC #6538) and all other Gram-positive challenge strains (i.e., *Staphylococcus aureus* [ATCC #29213], *Staphylococcus epidermidis* [ATCC #12228], *Micrococcus luteus* [ATCC #7468], and *Enterococcus faecalis* [ATCC #29212]), the 10<sup>-4</sup> plated dilutions were considered to be the lowest dilutions reliable for calculation of post-exposure populations.
- 11.4 When challenged with *Escherichia coli* (ATCC #11229) and *Staphylococcus aureus* (ATCC #6538), the antimicrobial properties of Product #3 (reference Section 7.0) were effectively neutralized at all dilutions plated.

12.0 ORIGIN OF CLINICAL ISOLATES - TABLE I:

Table I presents the origin of each of the Clinical Isolates used for this evaluation.

**TABLE I: ORIGIN OF CLINICAL ISOLATES**

Organism	Date Isolated	Specimen	Patient Age/Sex	Source	BSLI ID No.
<i>Acinetobacter</i> species	2001	respiratory	48/F	JG	061901Ab3
<i>Bacteroides fragilis</i>	2000	blood	70/F	JG	061901Bf6
<i>Candida albicans</i>	02/03/05	blood	75/F	JG	042905Ca
<i>Candida tropicalis</i>	01/02/05	blood	63/F	JG	042905Ct
<i>Enterobacter aeruginosa</i>	01/07/05	blood	68/M	JG	042905Ea
<i>Enterococcus faecalis</i>	2000	blood	75/M	JG	061901Efs2
<i>Enterococcus faecium</i>	2001	unknown	45/M	JG	061901Efm1
<i>Escherichia coli</i>	01/14/05	blood	32/M	JG	042905Ec1
<i>Escherichia coli</i>	01/05/05	blood	67/F	JG	042905Ec2
<i>Haemophilus influenzae</i>	2004	pulmonary	3/M	JMI	072605Hi
<i>Klebsiella oxytoca</i>	2001	unknown	81/M	JG	061901Ko1
<i>Klebsiella pneumoniae</i>	unknown	blood	unknown	JG	061901Kpn2
<i>Micrococcus luteus</i>	2000	blood	3/M	JG	061901MI2
<i>Proteus mirabilis</i>	2001	unknown	85/F	JG	061901Pm2
<i>Pseudomonas aeruginosa</i>	2004	blood	64/F	JMI	072605Pa
<i>Pseudomonas aeruginosa</i>	2001	pulmonary	52/F	JG	061901Pa2
<i>Serratia marcescens</i>	02/10/05	blood	71/F	JG	042905Sm
<i>Staphylococcus aureus</i>	2001	pulmonary	2/F	JG	061901Sa1
<i>Staphylococcus aureus</i>	2001	blood	51/F	JG	061901Sa2
<i>Staphylococcus epidermidis</i>	2004	blood	unknown	JMI	072605Se
<i>Staphylococcus haemolyticus</i>	01/27/05	pleural fluid	51/M	JG	042905Sha
<i>Staphylococcus hominis</i>	02/06/05	blood	62/M	JG	042905Sho
<i>Staphylococcus saprophyticus</i>	02/14/05	urine	67/M	JG	042905Ss
<i>Streptococcus pneumoniae</i>	2004	respiratory	unknown	JMI	072605Spn1
<i>Streptococcus pyogenes</i>	2001	unknown	unknown	JG	061901Spy7

**ABBREVIATIONS USED**

F = female  
 JMI = JMI Laboratories, North Liberty, Iowa  
 JG = Jones Group  
 M = male



13.0 **RESULTS - TABLES II THROUGH IV:**

Table II presents the Initial Populations (CFU/mL), the Post-Exposure Populations (CFU/mL), and the Log<sub>10</sub> and percent reductions observed for Product #1, Microcyn™ (Lot Number RDH103105-02) versus each of the fifty (50) microorganism strains evaluated. Table III presents the Initial Populations (CFU/mL), the Post-Exposure Populations (CFU/mL), and the Log<sub>10</sub> and percent reductions observed for Product #2, HIBICLENS® (Lot Number 505733) versus each of the ten (10) microorganism strains evaluated. Table IV presents the Initial Populations (CFU/mL), the Post-Exposure Populations (CFU/mL), and the Log<sub>10</sub> and percent reductions observed for Product #3, 0.9% Sodium Chloride Irrigation, USP (Lot Number G029462) versus each of the ten (10) microorganism strains evaluated.

**TABLE II**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
1	<i>Acinetobacter baumannii</i> (ATCC #19003)	2.340 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.3692	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.3692	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.3692	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.3692	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.3692	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.3692	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.3692	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.3692	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.3692	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.3692	99.9999%
2	<i>Acinetobacter baumannii</i> Clinical Isolate BSLI #061901Ab3	1.8150 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.2589	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.2589	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.2589	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.2589	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.2589	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.2589	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.2589	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.2589	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.2589	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.2589	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
3	<i>Bacteroides fragilis</i> (ATCC #43858)	4.40 x 10 <sup>10</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	7.6435	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	7.6435	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	7.6435	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	7.6435	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	7.6435	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	7.6435	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	7.6435	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	7.6435	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	7.6435	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	7.6435	99.9999%
4	<i>Bacteroides fragilis</i> Clinical Isolate BSLI #061901Bf6	2.70 x 10 <sup>10</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	7.4314	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	7.4314	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	7.4314	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	7.4314	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	7.4314	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	7.4314	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	7.4314	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	7.4314	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	7.4314	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	7.4314	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
5	<i>Candida albicans</i> (ATCC #10231)	2.160 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.3345	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.3345	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.3345	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.3345	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.3345	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.3345	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.3345	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.3345	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.3345	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.3345	99.9999%
6	<i>Candida albicans</i> Clinical Isolate BSLI #042905Ca	5.650 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.7520	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.7520	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.7520	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.7520	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.7520	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.7520	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.7520	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.7520	99.9999%
			15 minutes	1.250 x 10 <sup>4</sup>	5.6551	99.9998%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.7520	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
7	<i>Candida tropicalis</i> (ATCC #750)	6.750 x 10 <sup>9</sup>	30 seconds	1.4750 x 10 <sup>5</sup>	4.6605	99.9978%
			1 minute	1.3150 x 10 <sup>6</sup>	3.7104	99.9805%
			3 minutes	9.40 x 10 <sup>5</sup>	3.8562	99.9861%
			5 minutes	1.690 x 10 <sup>6</sup>	3.6014	99.9750%
			7 minutes	3.70 x 10 <sup>6</sup>	3.2611	99.9452%
			9 minutes	1.1950 x 10 <sup>6</sup>	3.7519	99.9823%
			11 minutes	7.750 x 10 <sup>5</sup>	3.9400	99.9885%
			13 minutes	9.550 x 10 <sup>5</sup>	3.8493	99.9859%
			15 minutes	1.210 x 10 <sup>5</sup>	4.7465	99.9982%
8	<i>Candida tropicalis</i> Clinical Isolate BSLI #042905Ct	1.850 x 10 <sup>9</sup>	20 minutes	3.90 x 10 <sup>4</sup>	5.2382	99.9994%
			30 seconds	1.230 x 10 <sup>5</sup>	4.1773	99.9934%
			1 minute	1.0150 x 10 <sup>5</sup>	4.2607	99.9945%
			3 minutes	8.90 x 10 <sup>5</sup>	3.3178	99.9519%
			5 minutes	2.050 x 10 <sup>6</sup>	2.9554	99.8892%
			7 minutes	1.360 x 10 <sup>6</sup>	3.1337	99.9265%
			9 minutes	9.450 x 10 <sup>6</sup>	2.2918	99.4892%
			11 minutes	4.850 x 10 <sup>6</sup>	2.5815	99.7378%
			13 minutes	4.30 x 10 <sup>6</sup>	2.6337	99.7676%
			15 minutes	4.10 x 10 <sup>6</sup>	2.6544	99.7784%
20 minutes	7.30 x 10 <sup>5</sup>	3.4039	99.9605%			

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
9	<i>Enterobacter aerogenes</i> (ATCC #29007)	1.2250 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.0881	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.0881	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.0881	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.0881	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.0881	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.0881	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.0881	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.0881	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.0881	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.0881	99.9999%
10	<i>Enterobacter aerogenes</i> Clinical Isolate BSLI #042905Ea	1.0150 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.0065	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.0065	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.0065	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.0065	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.0065	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.0065	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.0065	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.0065	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.0065	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.0065	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
11	<i>Enterococcus faecalis</i> (ATCC #29212)	2.610 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.4166	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.4166	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.4166	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.4166	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.4166	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.4166	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.4166	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.4166	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.4166	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.4166	99.9999%
12	<i>Enterococcus faecalis</i> Clinical Isolate BSLI #061901Efs2	1.2850 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.1089	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.1089	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.1089	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.1089	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.1089	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.1089	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.1089	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.1089	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.1089	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.1089	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
13	<i>Enterococcus faecium</i> VRE, MDR (ATCC #51559)	3.250 x 10 <sup>9</sup> ● 2.70 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.5119	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.5119	99.9999%
			● 3 minutes	< 1.00 x 10 <sup>3</sup>	6.4314	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.5119	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.5119	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.5119	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.5119	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.5119	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.5119	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.5119	99.9999%
14	<i>Enterococcus faecium</i> Clinical Isolate BSLI #061901Efin1	1.130 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.0531	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.0531	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.0531	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.0531	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.0531	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.0531	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.0531	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.0531	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.0531	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.0531	99.9999%

VRE = Vancomycin-Resistant *Enterococcus*

MDR = Multi-Drug Resistant

● = Time point and challenge suspension which were evaluated on a second test date.

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
15	<i>Escherichia coli</i> (ATCC #11229)	5.00 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.6990	99.9998%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.6990	99.9998%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.6990	99.9998%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.6990	99.9998%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.6990	99.9998%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.6990	99.9998%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.6990	99.9998%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.6990	99.9998%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.6990	99.9998%
16	<i>Escherichia coli</i> Clinical Isolate BSLI #042905Ec1	3.950 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.5966	99.9997%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.5966	99.9997%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.5966	99.9997%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.5966	99.9997%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.5966	99.9997%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.5966	99.9997%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.5966	99.9997%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.5966	99.9997%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.5966	99.9997%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.5966	99.9997%



**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
17	<i>Escherichia coli</i> (ATCC #25922)	6.650 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
18	<i>Escherichia coli</i> Clinical Isolate BSLI #042905Ec2	7.40 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.8692	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.8692	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.8692	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.8692	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.8692	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.8692	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.8692	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.8692	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.8692	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.8692	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
19	<i>Haemophilus influenzae</i> (ATCC #8149)	1.5050 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			1 minute	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			3 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			5 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			7 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			9 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			11 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			13 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			15 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			20 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
20	<i>Haemophilus influenzae</i> Clinical Isolate BSLI #072605Hi	1.90 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>4</sup>	5.2788	99.9995%
			1 minute	< 1.00 x 10 <sup>4</sup>	5.2788	99.9995%
			3 minutes	< 1.00 x 10 <sup>4</sup>	5.2788	99.9995%
			5 minutes	< 1.00 x 10 <sup>4</sup>	5.2788	99.9995%
			7 minutes	< 1.00 x 10 <sup>4</sup>	5.2788	99.9995%
			9 minutes	< 1.00 x 10 <sup>4</sup>	5.2788	99.9995%
			11 minutes	< 1.00 x 10 <sup>4</sup>	5.2788	99.9995%
			13 minutes	< 1.00 x 10 <sup>4</sup>	5.2788	99.9995%
			15 minutes	< 1.00 x 10 <sup>4</sup>	5.2788	99.9995%
			20 minutes	< 1.00 x 10 <sup>4</sup>	5.2788	99.9995%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
21	<i>Klebsiella oxytoca</i> MDR (ATCC #15764)	1.120 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.0492	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.0492	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.0492	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.0492	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.0492	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.0492	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.0492	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.0492	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.0492	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.0492	99.9999%
22	<i>Klebsiella oxytoca</i> Clinical Isolate BSLI #061901K01	1.810 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.2577	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.2577	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.2577	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.2577	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.2577	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.2577	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.2577	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.2577	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.2577	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.2577	99.9999%

MDR = Multi-Drug Resistant

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
23	<i>Klebsiella pneumoniae</i> subsp. <i>ozaenae</i> (ATCC #29019)	1.390 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.1430	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.1430	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.1430	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.1430	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.1430	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.1430	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.1430	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.1430	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.1430	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.1430	99.9999%
24	<i>Klebsiella pneumoniae</i> Clinical Isolate BSLI #061901Kpn2	9.950 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
25	<i>Micrococcus luteus</i> (ATCC #7468)	6.950 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.8420	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.8420	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.8420	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.8420	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.8420	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.8420	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.8420	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.8420	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.8420	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.8420	99.9999%
26	<i>Micrococcus luteus</i> Clinical Isolate BSLI #061901M12	1.5150 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.1804	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.1804	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.1804	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.1804	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.1804	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.1804	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.1804	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.1804	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.1804	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.1804	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
27	<i>Proteus mirabilis</i> (ATCC #7002)	1.5950 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.2028	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.2028	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.2028	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.2028	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.2028	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.2028	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.2028	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.2028	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.2028	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.2028	99.9999%
28	<i>Proteus mirabilis</i> Clinical Isolate BSLI #061901Pm2	2.0950 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.3212	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.3212	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.3212	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.3212	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.3212	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.3212	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.3212	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.3212	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.3212	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.3212	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
29	<i>Pseudomonas aeruginosa</i> (ATCC #15442)	6.450 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
30	<i>Pseudomonas aeruginosa</i> Clinical Isolate BSLI #072605Pa	1.3850 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.1414	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.1414	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.1414	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.1414	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.1414	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.1414	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.1414	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.1414	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.1414	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.1414	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
31	<i>Pseudomonas aeruginosa</i> (ATCC #27853)	5.550 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
32	<i>Pseudomonas aeruginosa</i> Clinical Isolate BSLI #061901Pa2	1.1650 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.0663	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.0663	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.0663	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.0663	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.0663	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.0663	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.0663	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.0663	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.0663	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.0663	99.9999%



**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
33	<i>Serratia marcescens</i> (ATCC #14756)	9.950 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9998%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
34	<i>Serratia marcescens</i> Clinical Isolate BSLI #042905Sm	3.6650 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.5641	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.5641	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.5641	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.5641	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.5641	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.5641	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.5641	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.5641	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.5641	99.9998%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.5641	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
35	<i>Staphylococcus aureus</i> (ATCC #6538)	1.5050 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.1775	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.1775	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.1775	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.1775	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.1775	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.1775	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.1775	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.1775	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.1775	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.1775	99.9999%
36	<i>Staphylococcus aureus</i> Clinical Isolate BSLI #061901Sa1	1.250 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.0969	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.0969	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.0969	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.0969	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.0969	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.0969	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.0969	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.0969	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.0969	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.0969	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
37	<i>Staphylococcus aureus</i> (ATCC #29213)	1.740 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.2405	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.2405	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.2405	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.2405	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.2405	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.2405	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.2405	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.2405	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.2405	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.2405	99.9999%
38	<i>Staphylococcus aureus</i> Clinical Isolate BSLI #061901Sa2	1.1050 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.0434	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.0434	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.0434	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.0434	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.0434	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.0434	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.0434	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.0434	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.0434	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.0434	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
39	<i>Staphylococcus epidermidis</i> (ATCC #12228)	1.0550 x 10 <sup>9</sup> ● 1.2650 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.0233	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.0233	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.0233	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.0233	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.0233	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.0233	99.9999%
			● 11 minutes	< 1.00 x 10 <sup>3</sup>	6.1021	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.0233	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.0233	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.0233	99.9999%
40	<i>Staphylococcus epidermidis</i> Clinical Isolate BSLI #072605Se	4.350 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.6385	99.9998%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.6385	99.9998%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.6385	99.9998%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.6385	99.9998%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.6385	99.9998%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.6385	99.9998%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.6385	99.9998%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.6385	99.9998%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.6385	99.9998%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.6385	99.9998%

● = Time point and challenge suspension which were evaluated on a second test date.

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
41	<i>Staphylococcus haemolyticus</i> (ATCC #29970)	8.150 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.9112	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.9112	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.9112	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.9112	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.9112	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.9112	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.9112	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.9112	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.9112	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.9112	99.9999%
42	<i>Staphylococcus haemolyticus</i> Clinical Isolate BSLI #042905Sha	8.350 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.9217	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.9217	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.9217	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.9217	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.9217	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.9217	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.9217	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.9217	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.9217	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.9217	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
43	<i>Staphylococcus hominis</i> (ATCC #27844)	2.790 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.4456	99.9996%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.4456	99.9996%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.4456	99.9996%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.4456	99.9996%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.4456	99.9996%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.4456	99.9996%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.4456	99.9996%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.4456	99.9996%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.4456	99.9996%
44	<i>Staphylococcus hominis</i> Clinical Isolate BSLI #042905Sho	5.20 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.7160	99.9998%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.7160	99.9998%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.7160	99.9998%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.7160	99.9998%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.7160	99.9998%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.7160	99.9998%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.7160	99.9998%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.7160	99.9998%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.7160	99.9998%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.7160	99.9998%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
45	<i>Staphylococcus saprophyticus</i> (ATCC #35552)	$9.10 \times 10^8$	30 seconds	$< 1.00 \times 10^3$	5.9590	99.9999%
			1 minute	$< 1.00 \times 10^3$	5.9590	99.9999%
			3 minutes	$< 1.00 \times 10^3$	5.9590	99.9999%
			5 minutes	$< 1.00 \times 10^3$	5.9590	99.9999%
			7 minutes	$< 1.00 \times 10^3$	5.9590	99.9999%
			9 minutes	$< 1.00 \times 10^3$	5.9590	99.9999%
			11 minutes	$< 1.00 \times 10^3$	5.9590	99.9999%
			13 minutes	$< 1.00 \times 10^3$	5.9590	99.9999%
			15 minutes	$< 1.00 \times 10^3$	5.9590	99.9999%
			20 minutes	$< 1.00 \times 10^3$	5.9590	99.9999%
46	<i>Staphylococcus saprophyticus</i> Clinical Isolate BSLI #042905Ss	$1.4150 \times 10^9$	30 seconds	$< 1.00 \times 10^3$	6.1508	99.9999%
			1 minute	$< 1.00 \times 10^3$	6.1508	99.9999%
			3 minutes	$< 1.00 \times 10^3$	6.1508	99.9999%
			5 minutes	$< 1.00 \times 10^3$	6.1508	99.9999%
			7 minutes	$< 1.00 \times 10^3$	6.1508	99.9999%
			9 minutes	$< 1.00 \times 10^3$	6.1508	99.9999%
			11 minutes	$< 1.00 \times 10^3$	6.1508	99.9999%
			13 minutes	$< 1.00 \times 10^3$	6.1508	99.9999%
			15 minutes	$< 1.00 \times 10^3$	6.1508	99.9999%
			20 minutes	$< 1.00 \times 10^3$	6.1508	99.9999%

**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
47	<i>Streptococcus pneumoniae</i> (ATCC #33400)	2.1450 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>4</sup>	5.3314	99.9995%
			1 minute	< 1.00 x 10 <sup>4</sup>	5.3314	99.9995%
			3 minutes	< 1.00 x 10 <sup>4</sup>	5.3314	99.9995%
			5 minutes	< 1.00 x 10 <sup>4</sup>	5.3314	99.9995%
			7 minutes	< 1.00 x 10 <sup>4</sup>	5.3314	99.9995%
			9 minutes	< 1.00 x 10 <sup>4</sup>	5.3314	99.9995%
			11 minutes	< 1.00 x 10 <sup>4</sup>	5.3314	99.9995%
			13 minutes	< 1.00 x 10 <sup>4</sup>	5.3314	99.9995%
			15 minutes	< 1.00 x 10 <sup>4</sup>	5.3314	99.9995%
			20 minutes	< 1.00 x 10 <sup>4</sup>	5.3314	99.9995%
48	<i>Streptococcus pneumoniae</i> Clinical Isolate BSLI #072605Spn1	3.550 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>4</sup>	4.5502	99.9972%
			1 minute	< 1.00 x 10 <sup>4</sup>	4.5502	99.9972%
			3 minutes	< 1.00 x 10 <sup>4</sup>	4.5502	99.9972%
			5 minutes	< 1.00 x 10 <sup>4</sup>	4.5502	99.9972%
			7 minutes	< 1.00 x 10 <sup>4</sup>	4.5502	99.9972%
			9 minutes	< 1.00 x 10 <sup>4</sup>	4.5502	99.9972%
			11 minutes	< 1.00 x 10 <sup>4</sup>	4.5502	99.9972%
			13 minutes	< 1.00 x 10 <sup>4</sup>	4.5502	99.9972%
			15 minutes	< 1.00 x 10 <sup>4</sup>	4.5502	99.9972%
			20 minutes	< 1.00 x 10 <sup>4</sup>	4.5502	99.9972%



**TABLE II (Continued)**  
 Product #1: Microcyn™ (Test Product)  
 Lot Number RDH103105-02, Expires 10/2006  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
49	<i>Streptococcus pyogenes</i> (ATCC #19615)	5.20 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.7160	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.7160	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.7160	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.7160	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.7160	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.7160	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.7160	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.7160	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.7160	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.7160	99.9999%
50	<i>Streptococcus pyogenes</i> Clinical Isolate BSLI #061901Spy7	2.5920 x 10 <sup>9</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	6.4141	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	6.4141	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	6.4141	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	6.4141	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	6.4141	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	6.4141	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	6.4141	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	6.4141	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	6.4141	99.9999%
			20 minutes	< 1.00 x 10 <sup>3</sup>	6.4141	99.9999%

**TABLE III**

Product #2: HIBICLENS® Chlorhexidine Gluconate Solution 4% (w/v) (Reference Product; Active Control)  
 Lot Number 505733, Expires 06/2007  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
1	<i>Enterococcus faecalis</i> (ATCC #29212)	$2.610 \times 10^9$	30 seconds	$6.550 \times 10^7$	1.6004	97.4904%
			1 minute	$8.950 \times 10^6$	2.4648	99.6571%
			3 minutes	$1.50 \times 10^4$	5.2405	99.9994%
			5 minutes	$< 1.00 \times 10^4$	5.4166	99.9996%
			7 minutes	$< 1.00 \times 10^4$	5.4166	99.9996%
			9 minutes	$< 1.00 \times 10^4$	5.4166	99.9996%
			11 minutes	$< 1.00 \times 10^4$	5.4166	99.9996%
			13 minutes	$< 1.00 \times 10^4$	5.4166	99.9996%
			15 minutes	$< 1.00 \times 10^4$	5.4166	99.9996%
			20 minutes	$< 1.00 \times 10^4$	5.4166	99.9996%
2	<i>Escherichia coli</i> (ATCC #11229)	$5.00 \times 10^8$	30 seconds	$< 1.00 \times 10^3$	5.6990	99.9998%
			1 minute	$< 1.00 \times 10^3$	5.6990	99.9998%
			3 minutes	$< 1.00 \times 10^3$	5.6990	99.9998%
			5 minutes	$< 1.00 \times 10^3$	5.6990	99.9998%
			7 minutes	$< 1.00 \times 10^3$	5.6990	99.9998%
			9 minutes	$< 1.00 \times 10^3$	5.6990	99.9998%
			11 minutes	$< 1.00 \times 10^3$	5.6990	99.9998%
			13 minutes	$< 1.00 \times 10^3$	5.6990	99.9998%
			15 minutes	$< 1.00 \times 10^3$	5.6990	99.9998%
			20 minutes	$< 1.00 \times 10^3$	5.6990	99.9998%

**TABLE III (Continued)**

Product #2: HIBICLENS® Chlorhexidine Gluconate Solution 4% (w/v) (Reference Product; Active Control)  
 Lot Number 505733, Expires 06/2007  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
3	<i>Escherichia coli</i> (ATCC #25922)	6.650 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.8228	99.9998%
4	<i>Micrococcus luteus</i> (ATCC #7468)	6.950 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>4</sup>	4.8420	99.9986%
			1 minute	< 1.00 x 10 <sup>4</sup>	4.8420	99.9986%
			3 minutes	< 1.00 x 10 <sup>4</sup>	4.8420	99.9986%
			5 minutes	< 1.00 x 10 <sup>4</sup>	4.8420	99.9986%
			7 minutes	< 1.00 x 10 <sup>4</sup>	4.8420	99.9986%
			9 minutes	< 1.00 x 10 <sup>4</sup>	4.8420	99.9986%
			11 minutes	< 1.00 x 10 <sup>4</sup>	4.8420	99.9986%
			13 minutes	< 1.00 x 10 <sup>4</sup>	4.8420	99.9986%
			15 minutes	< 1.00 x 10 <sup>4</sup>	4.8420	99.9986%
			20 minutes	< 1.00 x 10 <sup>4</sup>	4.8420	99.9986%

**TABLE III (Continued)**

Product #2: HIBICLENS® Chlorhexidine Gluconate Solution 4% (w/v) (Reference Product; Active Control)  
 Lot Number 505733, Expires 06/2007  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
5	<i>Pseudomonas aeruginosa</i> (ATCC #15442)	6.450 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.8096	99.9998%
6	<i>Pseudomonas aeruginosa</i> (ATCC #27853)	5.550 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.7443	99.9998%

**TABLE III (Continued)**

Product #2: HIBICLENS® Chlorhexidine Gluconate Solution 4% (w/v) (Reference Product; Active Control)  
 Lot Number 505733, Expires 06/2007  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
7	<i>Serratia marcescens</i> (ATCC #14756)	9.950 x 10 <sup>8</sup>	30 seconds	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			1 minute	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			3 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			5 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			7 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			9 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			11 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			13 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
			15 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9998%
			20 minutes	< 1.00 x 10 <sup>3</sup>	5.9978	99.9999%
8	<i>Staphylococcus aureus</i> (ATCC #6538)	1.5050 x 10 <sup>9</sup>	30 seconds	1.160 x 10 <sup>8</sup>	1.1130	92.2924%
			1 minute	2.5850 x 10 <sup>7</sup>	1.7650	98.2824%
			3 minutes	7.50 x 10 <sup>4</sup>	4.3024	99.9950%
			5 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			7 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			9 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			11 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			13 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			15 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%
			20 minutes	< 1.00 x 10 <sup>4</sup>	5.1775	99.9993%

**TABLE III (Continued)**

Product #2: HIBICLENS® Chlorhexidine Gluconate Solution 4% (w/v) (Reference Product; Active Control)  
 Lot Number 505733, Expires 06/2007  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
9	<i>Staphylococcus aureus</i> (ATCC #29213)	1.740 x 10 <sup>9</sup>	30 seconds	2.040 x 10 <sup>8</sup>	0.9309	88.2759%
			1 minute	4.20 x 10 <sup>7</sup>	1.6173	97.5862%
			3 minutes	2.70 x 10 <sup>5</sup>	3.8091	99.9845%
			5 minutes	1.00 x 10 <sup>4</sup>	5.2405	99.9994%
			7 minutes	< 1.00 x 10 <sup>4</sup>	5.2405	99.9994%
			9 minutes	< 1.00 x 10 <sup>4</sup>	5.2405	99.9994%
			11 minutes	< 1.00 x 10 <sup>4</sup>	5.2405	99.9994%
			13 minutes	< 1.00 x 10 <sup>4</sup>	5.2405	99.9994%
			15 minutes	< 1.00 x 10 <sup>4</sup>	5.2405	99.9994%
			20 minutes	< 1.00 x 10 <sup>4</sup>	5.2405	99.9994%
10	<i>Staphylococcus epidermidis</i> (ATCC #12228)	1.0550 x 10 <sup>9</sup> ● 1.2650 x 10 <sup>9</sup>	30 seconds	1.00 x 10 <sup>4</sup>	5.0233	99.9991%
			1 minute	< 1.00 x 10 <sup>4</sup>	5.0233	99.9991%
			3 minutes	< 1.00 x 10 <sup>4</sup>	5.0233	99.9991%
			5 minutes	< 1.00 x 10 <sup>4</sup>	5.0233	99.9991%
			● 7 minutes	< 1.00 x 10 <sup>4</sup>	5.1021	99.9992%
			9 minutes	< 1.00 x 10 <sup>4</sup>	5.0233	99.9991%
			● 11 minutes	< 1.00 x 10 <sup>4</sup>	5.1021	99.9992%
			13 minutes	< 1.00 x 10 <sup>4</sup>	5.0233	99.9991%
			15 minutes	< 1.00 x 10 <sup>4</sup>	5.0233	99.9991%
			20 minutes	< 1.00 x 10 <sup>4</sup>	5.0233	99.9991%

● = Time point and challenge suspension which were evaluated on a second test date.

**TABLE IV**

Product #3: 0.9% Sodium Chloride Irrigation, USP (Reference Product; Placebo Solution)  
 Lot Number G029462, Expires 06/2007  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
1	<i>Enterococcus faecalis</i> (ATCC #29212)	2.610 x 10 <sup>9</sup>	30 seconds	1.2550 x 10 <sup>9</sup>	0.3180	51.9157%
			1 minute	1.4750 x 10 <sup>9</sup>	0.2478	43.4866%
			3 minutes	1.510 x 10 <sup>9</sup>	0.2376	42.1456%
			5 minutes	1.5350 x 10 <sup>9</sup>	0.2305	41.1877%
			7 minutes	1.390 x 10 <sup>9</sup>	0.2736	46.7433%
			9 minutes	1.340 x 10 <sup>9</sup>	0.2895	48.6590%
			11 minutes	1.5650 x 10 <sup>9</sup>	0.2221	40.0383%
			13 minutes	1.3750 x 10 <sup>9</sup>	0.2783	47.3180%
			15 minutes	1.610 x 10 <sup>9</sup>	0.2098	38.3142%
			20 minutes	1.3550 x 10 <sup>9</sup>	0.2847	48.0843%
2	<i>Escherichia coli</i> (ATCC #11229)	5.00 x 10 <sup>8</sup>	30 seconds	5.850 x 10 <sup>8</sup>	0.0000	0.0000%
			1 minute	5.70 x 10 <sup>8</sup>	0.0000	0.0000%
			3 minutes	6.90 x 10 <sup>8</sup>	0.0000	0.0000%
			5 minutes	5.850 x 10 <sup>8</sup>	0.0000	0.0000%
			7 minutes	5.90 x 10 <sup>8</sup>	0.0000	0.0000%
			9 minutes	5.650 x 10 <sup>8</sup>	0.0000	0.0000%
			11 minutes	6.20 x 10 <sup>8</sup>	0.0000	0.0000%
			13 minutes	6.30 x 10 <sup>8</sup>	0.0000	0.0000%
			15 minutes	4.850 x 10 <sup>8</sup>	0.0133	3.0000%
			20 minutes	5.90 x 10 <sup>8</sup>	0.0000	0.0000%

**TABLE IV (Continued)**

Product #3: 0.9% Sodium Chloride Irrigation, USP (Reference Product; Placebo Solution)  
 Lot Number G029462, Expires 06/2007  
 99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
3	<i>Escherichia coli</i> (ATCC #25922)	$6.650 \times 10^8$	30 seconds	$8.30 \times 10^8$	0.0000	0.0000%
			1 minute	$8.00 \times 10^8$	0.0000	0.0000%
			3 minutes	$7.60 \times 10^8$	0.0000	0.0000%
			5 minutes	$7.00 \times 10^8$	0.0000	0.0000%
			7 minutes	$6.60 \times 10^8$	0.0000	0.0000%
			9 minutes	$7.150 \times 10^8$	0.0000	0.0000%
			11 minutes	$8.10 \times 10^8$	0.0000	0.0000%
			13 minutes	$6.80 \times 10^8$	0.0000	0.0000%
			15 minutes	$7.00 \times 10^8$	0.0000	0.0000%
			20 minutes	$8.80 \times 10^8$	0.0000	0.0000%
4	<i>Micrococcus luteus</i> (ATCC #7468)	$6.950 \times 10^8$	30 seconds	$4.10 \times 10^8$	0.2292	41.0072%
			1 minute	$3.350 \times 10^8$	0.3170	51.7986%
			3 minutes	$3.80 \times 10^8$	-0.2622	45.3237%
			5 minutes	$4.050 \times 10^8$	0.2345	41.7266%
			7 minutes	$5.20 \times 10^8$	0.1260	25.1799%
			9 minutes	$4.450 \times 10^8$	0.1936	35.9712%
			11 minutes	$3.50 \times 10^8$	0.2979	49.6403%
			13 minutes	$4.250 \times 10^8$	0.2136	38.8489%
			15 minutes	$3.10 \times 10^8$	0.3506	55.3957%
			20 minutes	$4.550 \times 10^8$	0.1840	34.5324%



**TABLE IV (Continued)**

Product #3: 0.9% Sodium Chloride Irrigation, USP (Reference Product; Placebo Solution)

Lot Number G029462, Expires 06/2007

99% (v/v) concentration

No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
5	<i>Pseudomonas aeruginosa</i> (ATCC #15442)	6.450 x 10 <sup>8</sup>	30 seconds	5.90 x 10 <sup>8</sup>	0.0387	8.5271%
			1 minute	4.80 x 10 <sup>8</sup>	0.1284	25.5814%
			3 minutes	5.050 x 10 <sup>8</sup>	0.1063	21.7054%
			5 minutes	5.20 x 10 <sup>8</sup>	0.0936	19.3798%
			7 minutes	4.750 x 10 <sup>8</sup>	0.1329	26.3566%
			9 minutes	5.60 x 10 <sup>8</sup>	0.0614	13.1783%
			11 minutes	4.40 x 10 <sup>8</sup>	0.1661	31.7829%
			13 minutes	5.00 x 10 <sup>8</sup>	0.1106	22.4806%
			15 minutes	5.20 x 10 <sup>8</sup>	0.0936	19.3798%
			20 minutes	4.550 x 10 <sup>8</sup>	0.1516	29.4574%
6	<i>Pseudomonas aeruginosa</i> (ATCC #27853)	5.550 x 10 <sup>8</sup>	30 seconds	5.20 x 10 <sup>8</sup>	0.0283	6.3063%
			1 minute	4.80 x 10 <sup>8</sup>	0.0631	13.5135%
			3 minutes	2.380 x 10 <sup>9</sup>	0.0000	0.0000%
			5 minutes	4.00 x 10 <sup>8</sup>	0.1422	27.9279%
			7 minutes	6.650 x 10 <sup>8</sup>	0.0000	0.0000%
			9 minutes	7.850 x 10 <sup>8</sup>	0.0000	0.0000%
			11 minutes	6.90 x 10 <sup>8</sup>	0.0000	0.0000%
			13 minutes	5.90 x 10 <sup>8</sup>	0.0000	0.0000%
			15 minutes	6.050 x 10 <sup>8</sup>	0.0000	0.0000%
			20 minutes	4.150 x 10 <sup>8</sup>	0.1263	25.2252%

**TABLE IV (Continued)**

Product #3: 0.9% Sodium Chloride Irrigation, USP (Reference Product; Placebo Solution)

Lot Number G029462, Expires 06/2007

99% (v/v) concentration

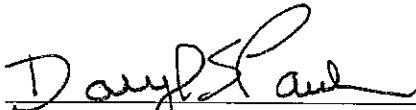
No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
7	<i>Serratia marcescens</i> (ATCC #14756)	$9.950 \times 10^8$	30 seconds	$1.2650 \times 10^9$	0.0000	0.0000%
			1 minute	$1.160 \times 10^9$	0.0000	0.0000%
			3 minutes	$1.120 \times 10^9$	0.0000	0.0000%
			5 minutes	$1.2750 \times 10^9$	0.0000	0.0000%
			7 minutes	$1.290 \times 10^9$	0.0000	0.0000%
			9 minutes	$1.1550 \times 10^9$	0.0000	0.0000%
			11 minutes	$1.2050 \times 10^9$	0.0000	0.0000%
			13 minutes	$1.1150 \times 10^9$	0.0000	0.0000%
			15 minutes	$1.1650 \times 10^9$	0.0000	0.0000%
			20 minutes	$1.110 \times 10^9$	0.0000	0.0000%
8	<i>Staphylococcus aureus</i> (ATCC #6538)	$1.5050 \times 10^9$	30 seconds	$1.670 \times 10^9$	0.0000	0.0000%
			1 minute	$1.440 \times 10^9$	0.0191	4.3189%
			3 minutes	$1.6150 \times 10^9$	0.0000	0.0000%
			5 minutes	$1.6150 \times 10^9$	0.0000	0.0000%
			7 minutes	$1.5650 \times 10^9$	0.0000	0.0000%
			9 minutes	$1.5850 \times 10^9$	0.0000	0.0000%
			11 minutes	$1.4150 \times 10^9$	0.0267	5.9801%
			13 minutes	$1.6250 \times 10^9$	0.0000	0.0000%
			15 minutes	$1.440 \times 10^9$	0.0191	4.3189%
			20 minutes	$1.510 \times 10^9$	0.0000	0.0000%

**TABLE IV (Continued)**  
 Product #3: 0.9% Sodium Chloride Irrigation, USP (Reference Product; Placebo Solution)  
 Lot Number G029462, Expires 06/2007  
 99% (v/v) concentration

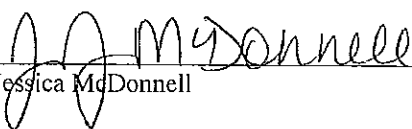
No.	Microorganism Species	Initial Population (CFU/mL)	Exposure Time	Post-Exposure Population (CFU/mL)	Log <sub>10</sub> Reduction	Percent Reduction
9	<i>Staphylococcus aureus</i> (ATCC #29213)	1.740 x 10 <sup>9</sup>	30 seconds	1.90 x 10 <sup>9</sup>	0.0000	0.0000%
			1 minute	1.9050 x 10 <sup>9</sup>	0.0000	0.0000%
			3 minutes	1.5650 x 10 <sup>9</sup>	0.0460	10.0575%
			5 minutes	1.6850 x 10 <sup>9</sup>	0.0139	3.1609%
			7 minutes	1.790 x 10 <sup>9</sup>	0.0000	0.0000%
			9 minutes	1.6950 x 10 <sup>9</sup>	0.0113	2.5862%
			11 minutes	1.630 x 10 <sup>9</sup>	0.0283	6.3218%
			13 minutes	1.7850 x 10 <sup>9</sup>	0.0000	0.0000%
			15 minutes	1.9450 x 10 <sup>9</sup>	0.0000	0.0000%
			20 minutes	1.510 x 10 <sup>9</sup>	0.0615	13.2184%
10	<i>Staphylococcus epidermidis</i> (ATCC #12228)	1.0550 x 10 <sup>9</sup>	30 seconds	9.50 x 10 <sup>8</sup>	0.0456	9.9526%
			1 minute	9.60 x 10 <sup>8</sup>	0.0410	9.0047%
			3 minutes	8.950 x 10 <sup>8</sup>	0.0715	15.1659%
			5 minutes	8.60 x 10 <sup>8</sup>	0.0888	18.4834%
			7 minutes	1.040 x 10 <sup>9</sup>	0.0063	1.4218%
			9 minutes	9.10 x 10 <sup>8</sup>	0.0643	13.7441%
			11 minutes	1.0050 x 10 <sup>9</sup>	0.0211	4.7393%
			13 minutes	8.150 x 10 <sup>8</sup>	0.1121	22.7488%
			15 minutes	9.80 x 10 <sup>8</sup>	0.0321	7.1090%
			20 minutes	8.30 x 10 <sup>8</sup>	0.1042	21.3270%

14.0 ACCEPTANCE:

**BIOSCIENCE LABORATORIES, INC.**  
300 N. Willson Avenue  
Bozeman, Montana 59715

President and CEO:  12-7-05  
Daryl S. Paulson, Ph.D. Date

Principal Study Director:  12/08/05  
Terri Eastman Date of Study Completion

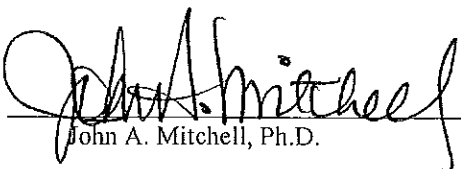
Associate Study Director:  12/08/05  
Jessica McDonnell Date

QUALITY ASSURANCE STATEMENT:

This study was inspected by the Quality Assurance Unit, and reports were submitted to the Study Director and Management in accordance with Standard Operating Procedures, as follows:

<u>Phase</u>	<u>Date</u>
Neutralization Assay	11/03/05
Product Testing	11/03/05, 11/08/05, and 11/15/05
Data Audit	12/06/05
Final Report Review	12/07/05
Reports to Study Director and Management	11/03/05, 11/08/05, 11/15/05, and 12/07/05

This study was conducted in compliance with Good Laboratory Practices standards, as described by the FDA (21 CFR Part 58), with the following exception: test article preparations were not analyzed at BioScience Laboratories, Inc., to confirm concentration, stability, or homogeneity.

Director of Quality Assurance:  12/07/05  
John A. Mitchell, Ph.D. Date

## INDEX OF ADDENDA

- I Protocol #050812-201  
Protocol Amendment Form (Form No. 94-G-006)
  
- II Product Information
  - Product Receipt Logs (Form No. 92-L-023)
  - Product-Tracking Forms (Form No. 93-L-029)
  
- III Inoculum Preparation Tracking Forms (Form No. 00-L-005)
  
- IV Neutralization Evaluation
  - General Data Gathering Sheets (Form No. 91-L-002) for Neutralization Evaluation
  - Neutralization Evaluation Forms (Form No. 91-L-013)
  - Neutralization Statistics
  
- V Media/Diluent Tracking Forms (Form No. 97-L-007)
  
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  - Equipment Tracking Forms (Form No. 98-L-007)
  - Water Bath Temperature Recording Forms (Form No. 95-L-007)
  - Incubator Log Forms (Form No. 96-L-008)
  - CO<sub>2</sub> Incubator Log Forms (Form No. 01-L-004)
  - Refrigerator Log Forms (Form No. 96-L-015)