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April 27, 2016

FINAL REPORT #160136-204

**A CHLORINE EQUIVALENCY EVALUATION OF ONE TEST PRODUCT**

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Prepared for:

**GLOBAL ENVIRONMENTAL RESTORATION (SPONSOR)**  
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Prepared by:

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## EXECUTIVE SUMMARY

**STUDY NUMBER:** 160136-204

**TITLE:** A CHLORINE EQUIVALENCY EVALUATION OF ONE TEST PRODUCT

**SPONSOR:** GLOBAL ENVIRONMENTAL RESTORATION  
P.O. Box 667  
Carencro, Louisiana 70520

**TESTING FACILITY:** BIOSCIENCE LABORATORIES, INC.  
1755 South 19th Avenue  
Bozeman, Montana 59718

**STUDY INITIATION DATE:** 03/09/2016

**STUDY COMPLETION DATE:** 04/27/2016

A chlorine-equivalency evaluation of three batches of one test product was performed using a modification of the AOAC Official Method 955.16, *Chlorine (Available) in Disinfectants - Germicidal Equivalent Concentration* (2005). The antibacterial activity of the three batches of test product when challenged with *Salmonella enterica enterica* serovar Typhi (ATCC #6539) and *Staphylococcus aureus aureus* (ATCC #6538) was compared for equivalency to the activity of standard solutions containing 50 ppm, 100 ppm, and 200 ppm of available chlorine.

All control criteria were met for both the challenge microorganisms; challenge suspension purity, growth, and sterility of all media used for testing. The neutralization criteria were met for both the challenge microorganisms when challenged with the test products as well as the chlorine standard.

To be considered equivalent in germicidal activity to standard solutions containing 50 ppm, 100 ppm, and/or 200 ppm available chlorine, the test products must show absence of growth in as many consecutive tubes of the subculture series as the 50 ppm, 100 ppm, and/or 200 ppm chlorine standard solutions, respectively. The test results were considered valid since the resistance of both test cultures to the 50 ppm chlorine standard was such that there was at least one subculture tube at the beginning of the series negative for growth and the resistance of both test cultures to the 200 ppm chlorine standard was such that there was at least one subculture tube at the end of the series positive for growth.

Test Batch #1, SNIpER Disinfectant (Lot Number 109-195-1F) diluted in 125 ppm Synthetic Hard Water in a ratio of 1:6, was determined to be more efficacious in germicidal efficacy than the 200 ppm Chlorine Standard Solution when challenged with *Salmonella enterica enterica* serovar Typhi (ATCC #6539) and *Staphylococcus aureus aureus* (ATCC #6538).

Test Product #2, SNIpER Disinfectant (Lot Number 109-195-2F) diluted in 125 ppm Synthetic Hard Water in a ratio of 1:6, was determined to be more efficacious in germicidal efficacy than the 200 ppm Chlorine Standard Solution when challenged with *Salmonella enterica enterica* serovar Typhi (ATCC #6539) and *Staphylococcus aureus aureus* (ATCC #6538).

Test Product #3, SNIpER Disinfectant (Lot Number 109-195-3F) diluted in 125 ppm Synthetic Hard Water in a ratio of 1:6, was determined to be more efficacious in germicidal efficacy than the 200 ppm Chlorine Standard Solution when challenged with *Salmonella enterica enterica* serovar Typhi (ATCC #6539) and *Staphylococcus aureus aureus* (ATCC #6538).

April 27, 2016

FINAL REPORT #160136-204

- 1.0 **TITLE:** A CHLORINE EQUIVALENCY EVALUATION OF ONE TEST PRODUCT
- 2.0 **SPONSOR:** GLOBAL ENVIRONMENTAL RESTORATION  
P.O. Box 667  
Carencro, Louisiana 70520
- 3.0 **TESTING FACILITY:** BIOSCIENCE LABORATORIES, INC.  
1755 South 19th Avenue  
Bozeman, Montana 59718
- 4.0 **STUDY DIRECTOR:** Lexxy Bueling, M.S.

5.0 **PURPOSE:**

This evaluation determined the relative antibacterial efficacy of three test products when compared to the efficacy of sodium hypochlorite (NaOCl) standard solutions containing 50, 100, and 200 parts per million (ppm) of available chlorine. The product and NaOCl Standard Solutions were evaluated versus *Salmonella enterica enterica* serovar Typhi (ATCC #6539) and *Staphylococcus aureus aureus* (ATCC #6538). All testing was performed in accordance with Good Laboratory Practices, as specified in 40 CFR Part 160, with two exceptions. The chemical characterization of the test products thereof were not performed by the Testing Facility (GLP 160.105 and GLP 160.113). The Study Sponsor retained responsibility for the determination of the identity, strength, purity, composition, and stability of the test products.

6.0 **SCOPE:**

A chlorine-equivalency evaluation of three test products was performed using a modification of the AOAC Official Method 955.16, *Chlorine (Available) in Disinfectants - Germicidal Equivalent Concentration* (2005), as specified in the NSF's *Registration Guidelines for Proprietary Substances and Nonfood Compounds* (2013). The antibacterial activity of the three test products versus *Salmonella enterica enterica* serovar Typhi (ATCC #6539) and *Staphylococcus aureus aureus* (ATCC #6538) was compared for equivalency to the activity of standard solutions containing 50 ppm, 100 ppm, and 200 ppm of available chlorine.

The Study Protocol, included as Addendum 1 of this Final Report, presents the study methodology, in detail, as do the Data Gathering Forms in Addendum 5 of this Final Report. No deviations from the methodology described in the Study Protocol occurred during the course of this evaluation. One deviation from applicable BioScience Laboratories Standard Operating Procedures occurred during the course of this evaluation. (reference Section 15.0 of this Final Report); as is detailed on Protocol and/or SOP Deviation Recording Form (Form No. 99-QA-004) in Addendum 1 of this Final Report, there were no adverse effects upon the study outcome

7.0 **STUDY DATES:**

**STUDY INITIATION DATE:** 03/09/2016

**EXPERIMENTAL START DATE:** 03/15/2016

**EXPERIMENTAL END DATE:** 04/08/2016

**STUDY COMPLETION DATE:** 04/27/2016

## 8.0 TEST MATERIALS:

The test products were provided to the Testing Facility by the Study Sponsor. Responsibility for determination of the identity, strength, purity, composition, stability, and solubility of the test products, as well as responsibility for the retention of the test products, remained with the Sponsor. All documentation provided with the test products is included in Addendum 2 of this Final Report.

Test Batch #1: SNiPER Disinfectant  
Lot Number: 109-195-1F  
Manufacture Date: 03/07/2016  
Expiration Date: 03/06/2017  
Active Ingredient: Chlorine Dioxide

Test Batch #2: SNiPER Disinfectant  
Lot Number: 109-195-2F  
Manufacture Date: 03/07/2016  
Expiration Date: 03/06/2017  
Active Ingredient: Chlorine Dioxide

Test Batch #3: SNiPER Disinfectant  
Lot Number: 109-195-3F  
Manufacture Date: 03/07/2016  
Expiration Date: 03/06/2017  
Active Ingredient: Chlorine Dioxide

## 9.0 CHALLENGE SPECIES:

The challenge bacterial species (American Type Culture Collection [ATCC] strain) evaluated were:

- 9.1 *Salmonella enterica enterica* serovar Typhi (ATCC #6539)
- 9.2 *Staphylococcus aureus aureus* (ATCC #6538)

## 10.0 EQUIPMENT AND SUPPLIES:

The equipment and supplies used in this study are as described in the Study Protocol in Addendum 1 of this Final Report. Additional details are recorded on Equipment Tracking Forms (Form No. 98-L-007) in Addendum 6 of this Final Report. All applicable equipment and instrumentation were calibrated in accordance with BioScience Laboratories, Inc., Standard Operating Procedures.

## 11.0 MEDIA:

The growth media and diluting fluids used in this study are as described in the Study Protocol in Addendum 1 of this Final Report. Additional details are recorded on a Media/Diluent Tracking Form (Form No. 97-L-007) in Addendum 6 of this Final Report.

## 12.0 INTERPRETATION OF RESULTS/ACCEPTANCE CRITERIA:

### Test Substance Performance Criteria

To be considered equivalent in germicidal activity to standard solutions containing 50 ppm, 100 ppm, and/or 200 ppm available chlorine, the test products must show absence of growth in as many consecutive tubes of the subculture series as the 50 ppm, 100 ppm, and/or 200 ppm standard solutions, respectively. The test results were considered valid since the resistance of both test cultures to the 50 ppm chlorine standard was such that there was at least one subculture tube at the beginning of the series negative for growth and the resistance of both test cultures to the 200 ppm chlorine standard was such that there was at least one subculture tube at the end of the series positive for growth.

Control Acceptance Criteria

All control criteria were met for both challenge microorganisms; challenge suspension purity, growth, and sterility of all media used for testing. The neutralization criteria were met for both the challenge microorganisms when challenged with the test products and the chlorine standard.

**13.0 NEUTRALIZATION RESULTS – TABLES 1 THROUGH 10:**

The results of the Neutralization Confirmation Controls prepared for each test strain indicated that the subculture medium (Fluid Thioglycollate Medium [FTM] and Lethen Broth [LB]) was effective in neutralizing the antimicrobial activity of the chlorine standards and the test products. Growth of each test strain was observed following inoculation with ≤ 100 colony-forming units (CFU); hence, this Study Acceptance Criterion was met.

The results of the Neutralization Confirmation Controls for *Salmonella enterica enterica* serovar Typhi (ATCC #6539) are presented in Tables 1 through 5. The results of the Neutralization Confirmation Controls for *Staphylococcus aureus aureus* (ATCC #6538) are presented in Tables 6 through 10.

**TABLE 1: NEUTRALIZATION INOCULUM LEVEL**

Test Strain	Colony-Forming Units (CFU) per mL
<i>Salmonella enterica enterica</i> serovar Typhi (ATCC #6539)	6.450 x 10 <sup>8</sup>

**TABLE 2: NEUTRALIZATION RESULTS**

Test Formulation: 200 ppm Chlorine Standard

Test Strain	Replicate	Inoculum Level (Average CFU)	Results (+) Growth / (-) No Growth	Acceptance Criteria Met? (Pass / Fail)
<i>Salmonella enterica enterica</i> serovar Typhi (ATCC #6539)	1	TNTC	+	PASS
	2		+	
	1	64.50	+	PASS
	2		+	
	1	4.50	+	PASS
	2		+	

(+) = growth (turbidity); all + growth results confirmed as challenge microorganism via iso-streaking and Gram-staining

(-) = no growth (no turbidity)

**TABLE 3: NEUTRALIZATION RESULTS**

Test Batch #1: SNIpER Disinfectant, Lot Number 109-195-1F  
 Manufactured Date: 03/07/2016

Test Strain	Replicate	Inoculum Level (Average CFU)	Results (+) Growth / (-) No Growth	Acceptance Criteria Met? (Pass / Fail)
<i>Salmonella enterica enterica</i> serovar Typhi (ATCC #6539)	1	TNTC	+	PASS
	2		+	
	1	64.50	+	PASS
	2		+	
	1	4.50	+	PASS
	2		+	

(+) = growth (turbidity); all + growth results confirmed as challenge microorganism via iso-streaking and Gram-staining  
 (-) = no growth (no turbidity)

**TABLE 4: NEUTRALIZATION RESULTS**

Test Batch #2: SNIpER Disinfectant, Lot Number 109-195-2F  
 Manufactured Date: 03/07/2016

Test Strain	Replicate	Inoculum Level (Average CFU)	Results (+) Growth / (-) No Growth	Acceptance Criteria Met? (Pass / Fail)
<i>Salmonella enterica enterica</i> serovar Typhi (ATCC #6539)	1	TNTC	+	PASS
	2		+	
	1	64.50	+	PASS
	2		+	
	1	4.50	+	PASS
	2		+	

(+) = growth (turbidity); all + growth results confirmed as challenge microorganism via iso-streaking and Gram-staining  
 (-) = no growth (no turbidity)

**TABLE 5: NEUTRALIZATION RESULTS**

Test Batch #3: SNIpER Disinfectant, Lot Number 109-195-3F  
 Manufactured Date: 03/07/2016

Test Strain	Replicate	Inoculum Level (Average CFU)	Results (+) Growth / (-) No Growth	Acceptance Criteria Met? (Pass / Fail)
<i>Salmonella enterica enterica</i> serovar Typhi (ATCC #6539)	1	TNTC	+	PASS
	2		+	
	1	64.50	+	PASS
	2		+	
	1	4.50	+	PASS
	2		+	

(+) = growth (turbidity); all + growth results confirmed as challenge microorganism via iso-streaking and Gram-staining  
 (-) = no growth (no turbidity)

**TABLE 6: NEUTRALIZATION INOCULUM LEVEL**

Test Strain	Colony-Forming Units (CFU) per mL
<i>Staphylococcus aureus aureus</i> (ATCC #6538)	9.00 x 10 <sup>7</sup>

**TABLE 7: NEUTRALIZATION RESULTS**

Test Formulation: 200 ppm Chlorine Standard

Test Strain	Replicate	Inoculum Level (Average CFU)	Results (+) Growth / (-) No Growth	Acceptance Criteria Met? (Pass / Fail)
<i>Staphylococcus aureus aureus</i> (ATCC #6538)	1	118.50	+	PASS
	2		+	
	1	9.00	+	PASS
	2		+	
	1	1.50	+	PASS
	2		+	

(+) = growth (turbidity); all + growth results confirmed as challenge microorganism via iso-streaking and Gram-staining  
 (-) = no growth (no turbidity)



**TABLE 8: NEUTRALIZATION RESULTS**

Test Batch #1: SNIpER Disinfectant, Lot Number 109-195-1F  
Manufactured Date: 03/07/2016

Test Strain	Replicate	Inoculum Level (Average CFU)	Results (+) Growth / (-) No Growth	Acceptance Criteria Met? (Pass / Fail)
<i>Staphylococcus aureus aureus</i> (ATCC #6538)	1	118.50	+	PASS
	2		+	
	1	9.00	+	PASS
	2		+	
	1	1.50	+	PASS
	2		-*	

(+) = growth (turbidity); all + growth results confirmed as challenge microorganism via iso-streaking and Gram-staining

(-) = no growth (no turbidity)

\*Tubes inoculated with extremely low populations (approximately 1 CFU) may exhibit “no growth” due to absence of organism in the sample. This will not be interpreted as a neutralization failure unless higher populations also demonstrate “no growth.”

**TABLE 9: NEUTRALIZATION RESULTS**

Test Batch #2: SNIpER Disinfectant, Lot Number 109-195-2F  
Manufactured Date: 03/07/2016

Test Strain	Replicate	Inoculum Level (Average CFU)	Results (+) Growth / (-) No Growth	Acceptance Criteria Met? (Pass / Fail)
<i>Staphylococcus aureus aureus</i> (ATCC #6538)	1	118.50	+	PASS
	2		+	
	1	9.00	+	PASS
	2		+	
	1	1.50	+	PASS
	2		-*	

(+) = growth (turbidity); all + growth results confirmed as challenge microorganism via iso-streaking and Gram-staining

(-) = no growth (no turbidity)

\*Tubes inoculated with extremely low populations (approximately 1 CFU) may exhibit “no growth” due to absence of organism in the sample. This will not be interpreted as a neutralization failure unless higher populations also demonstrate “no growth.”

**TABLE 10: NEUTRALIZATION RESULTS**

Test Batch #3: SNIpER Disinfectant, Lot Number 109-195-3F  
 Manufactured Date: 03/07/2016

Test Strain	Replicate	Inoculum Level (Average CFU)	Results (+) Growth / (-) No Growth	Acceptance Criteria Met? (Pass / Fail)
<i>Staphylococcus aureus aureus</i> (ATCC #6538)	1	118.50	+	PASS
	2		+	
	1	9.00	+	PASS
	2		+	
	1	1.50	+	PASS
	2		-*	

(+) = growth (turbidity); all + growth results confirmed as challenge microorganism via iso-streaking and Gram-staining

(-) = no growth (no turbidity)

\*Tubes inoculated with extremely low populations (approximately 1 CFU) may exhibit “no growth” due to absence of organism in the sample. This will not be interpreted as a neutralization failure unless higher populations also demonstrate “no growth.”

**14.0 CHLORINE EQUIVALENCY RESULTS – TABLES 11 AND 12:**

Table 11 summarizes the results of each subculture series for *Salmonella enterica enterica* serovar Typhi (ATCC #6539) for Test Batch #1, SNIpER Disinfectant (Lot Number 109-195-1F), Test Batch #2, SNIpER Disinfectant (Lot Number 109-195-2F), and Test Batch #3, SNIpER Disinfectant (Lot Number 109-195-3F), as well as for the 50 ppm, 100 ppm, and 200 ppm Chlorine Standard Solutions.

Table 12 summarizes the results of each subculture series for *Staphylococcus aureus aureus* (ATCC #6538) for Test Batch #1, SNIpER Disinfectant (Lot Number 109-195-1F), Test Batch #2, SNIpER Disinfectant (Lot Number 109-195-2F), and Test Batch #3, SNIpER Disinfectant (Lot Number 109-195-3F), as well as for the 50 ppm, 100 ppm, and 200 ppm Chlorine Standard Solutions.

**TABLE 11: CHLORINE EQUIVALENCY RESULTS**  
 Test Strain: *Salmonella enterica enterica* serovar Typhi (ATCC #6539)

Product	SUBCULTURE SERIES (Tube # / Time Subcultured after Initial Inoculation at Time = 0)									
	#1 1 minute	#2 2.5 minute	#3 4 minute	#4 5.5 minute	#5 7 minute	#6 8.5 minute	#7 10 minute	#8 11.5 minute	#9 13 minute	#10 14.5 minute
50 ppm Chlorine Standard	-	-	-	+	+	+	+	+	+	+
100 ppm Chlorine Standard	-	-	-	-	+	+	+	+	+	+
200 ppm Chlorine Standard	-	-	-	-	-	-	-	+	+	+
<b>Test Batch #1:</b> SNiPER Disinfectant Lot Number: 109-195-1F	-	-	-	-	-	-	-	-	-	-
<b>Test Batch #2:</b> SNiPER Disinfectant Lot Number: 109-195-2F	-	-	-	-	-	-	-	-	-	-
<b>Test Batch #3:</b> SNiPER Disinfectant Lot Number: 109-195-3F	-	-	-	-	-	-	-	-	-	-

(+) = growth (turbidity); all + growth results confirmed as challenge microorganism via iso-streaking and Gram-staining  
 (-) = no growth (no turbidity)

**TABLE 12: CHLORINE EQUIVALENCY RESULTS**  
 Test Strain: *Staphylococcus aureus aureus* (ATCC #6538)

Product	SUBCULTURE SERIES (Tube # / Time Subcultured after Initial Inoculation at Time = 0)									
	#1 1 minute	#2 2.5 minute	#3 4 minute	#4 5.5 minute	#5 7 minute	#6 8.5 minute	#7 10 minute	#8 11.5 minute	#9 13 minute	#10 14.5 minute
50 ppm Chlorine Standard	-	-	-	-	+	+	+	+	+	+
100 ppm Chlorine Standard	-	-	-	-	+	+	+	+	+	+
200 ppm Chlorine Standard	-	-	-	-	-	-	-	-	+	+
<b>Test Batch #1:</b> SNiPER Disinfectant Lot Number: 109-195-1F	-	-	-	-	-	-	-	-	-	-
<b>Test Batch #2:</b> SNiPER Disinfectant Lot Number: 109-195-2F	-	-	-	-	-	-	-	-	-	-
<b>Test Batch #3:</b> SNiPER Disinfectant Lot Number: 109-195-3F	-	-	-	-	-	-	-	-	-	-

(+) = growth (turbidity); all + growth results confirmed as challenge microorganism via iso-streaking and Gram-staining  
 (-) = no growth (no turbidity)

**15.0 DEVIATION FROM PROTOCOL:**

SOP QA-0004, Section 3.2.5 states the Quality Assurance Unit (QAU) will “Inspect each study at critical intervals... The frequency of QAU auditing will be dependent on the type and duration of the study but will be at a minimum on the first day of testing, if possible, and approximately once every 30 days after that.” The QAU was inadvertently not contacted at the time of Neutralization Confirmation testing on the first day of testing. The Neutralization Confirmation portion of the study was retested; at the time of the retest the QAU was present to audit the procedure. Due to variable results, the Neutralization Confirmation from the first day of testing are considered “For File Only” and will not be reported in the final report for the study – only the Neutralization Confirmation retest results are reported; as such the deviation had no adverse effect on the study outcome.

#### 16.0 LABORATORY PERSONNEL:

The following employees of BioScience Laboratories, Inc., were involved in the testing or ancillary support of this Study. The laboratory personnel have been appropriately trained, and their training records are on-file at the Testing Facility.

STUDY DIRECTOR:	Lexxy Bueling, M.S. Microbiologist
Stephen Antonich In-Vitro Laboratory Technician	Jessica McDonnell-Philipp Microbiologist
Dan Dragotoiu Microbiologist	Grady Wertman Microbiologist
Terri Eastman Manager of In-Vitro Laboratories	Kristy Weaver Microbiologist
Lisa Lehman Senior Microbiologist	Alyssa Yeik Microbiologist
Stephanie Cebulla Laboratory Support Technician	Jennifer Robinson Laboratory Support Technician
Marc Charnholm Manager of Laboratory Support	Michelle Chandler Product Handler

#### 17.0 QUALITY ASSURANCE AND QUALITY CONTROL PERSONNEL:

Danielle Goveia Quality Assurance Specialist	Kim Potter Quality Assurance Associate
Aaron Hoffman QC/Maintenance Specialist	Carl Schmidt ISO Technical Manager (QC, Training, Safety)
Amy L. Juhnke, RQAP-GLP Manager of Quality Assurance	

#### 18.0 QUALITY ASSURANCE AUDITS/FINDINGS:

The Quality Assurance Unit (QAU) conducted an in-phase audit of the critical test procedures over the course of testing, and advised the Study Director and Management of the outcome of this. On completion of testing, the QAU performed an audit of the raw data and of the Final Report, in its entirety. No deviations from the Study Protocol occurred during the course of this evaluation. One deviation from BioScience Laboratories, Inc., Standard Operating Procedure (SOP) occurred during the course of this evaluation (reference Section 15.0 of this Final Report) and was documented appropriately.

#### 19.0 DOCUMENTATION AND RECORD-KEEPING:

All documentation and records were compiled, analyzed, and retained by BioScience Laboratories, Inc. at its facility in Bozeman, Montana. All raw data for this study, as well as the Final Report, will be retained in safe storage by the Testing Facility for a period of at least 5 years. BioScience Laboratories, Inc. will notify the Study Sponsor before any documents or records are destroyed.

20.0 ACCEPTANCE:

**BIOSCIENCE LABORATORIES, INC.**  
1755 South 19th Avenue  
Bozeman, Montana 59718

President and CEO:  04-26-16  
Daryl S. Paulson, Ph.D. Date

Study Director:  04/27/16  
Lexxy Buehling, M.S. Study Completion 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:

Phase Inspected	Audit Date	Date reported to Study Director	Date reported to Management
Neutralization Testing	04/05/2016	04/05/2016	04/08/2016
Product Testing	03/15/2016	03/16/2016	03/16/2016
Data Audit	04/25/2016	04/25/2016	04/26/2016
Final Report Review	04/25/2016	04/25/2016	04/26/2016

This study was conducted in compliance with Good Laboratory Practices standards, as described by the FDA (21 CFR Part 58), with the exception that the characterization of the identity, strength, purity, composition, stability, and solubility of the test products was not performed by BioScience Laboratories, Inc. A deviation to the Study Protocol was documented appropriately. This statement also serves to confirm that the Final Report reflects the raw data.

Quality Assurance Specialist:  04/26/16  
Danielle Goveia Date

## INDEX OF ADDENDA

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