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REPORT No.

G-37528

04/03/01

EDUCATION *Ph.D. Supervised*
EXPERIENCE *Serving since 1970*
EXTRAORDINARY *Upstream QA™*
Speed Reports
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LABORATORY REPORT

EXCELLENCE = GIBRALTAR

Study Title

EPA Food Contact Sanitizer Test for Previously Cleaned Food Contact Surfaces
(AOAC Germicidal and Detergent Sanitizing Action of Disinfectants)

Product Identity

BioSide HS 15%

Data Requirement

EPA Pesticide Assessment Guidelines Subdivision G, 1982, 91-2.

Author

Daniel L. Prince, Ph.D.
President

Study Completion Date

March 30, 2001

Testing Facility

Gibraltar Laboratories, Inc.
13504-C South Point Boulevard
Charlotte, NC 28273-6763

Laboratory Project Number (Study File)

GBL Study # GR 1683

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1. No claim of confidentiality under FIFRA 10(d)(1)(A),(B), or (C)

Statement of No Data Confidentiality Claims

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA 10(d)(1)(A), (B), or (C).

Company Enviro Tech Chemical Services Inc

Company Agent MIKE HARVEY Date 4-24-01
President Michael Harvey
Title Signature

2. Claim of confidentiality under FIFRA 10(d)(1)(A),(B), or (C)

Statement of Data Confidentiality Claims

Information claimed confidential on the basis of its falling within the scope of FIFRA 10(d)(1)(A),(B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study.

Company Enviro Tech
Company Agent _____ Date _____

Title Signature

Note: Applicants for permanent or temporary tolerances should note that it is OPP Policy that no permanent or temporary tolerance petition or request for an emergency exemption, that incorporates an analytical method, can be approved unless the applicant waives all claims of confidentiality for the analytical method. These analytical methods are published in the FDA Analytical Methods Manual, and therefore cannot be claimed as confidential. OPP implements this policy by returning submitted analytical methods (for which confidentiality claims have been made) to the submitter, to obtain the confidentiality waiver before they can be processed.

*Gibraltar Laboratories, Inc. is not aware of what, if any, data will be classified as confidential. Accordingly, this page is left blank for the sponsor to complete.



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GLP Compliance Statement

This study was conducted in accordance with the principles of Good Laboratory Practices (GLP) as promulgated by the following regulatory agency:

40 CFR Ch.1 (7-1-99 edition) Part 160 Good Laboratory Practice Standards (EPA - FIFRA Pesticides).

Study No.: GR 1683

Protocol No.: 2248

This study meets the requirements for 40 CFR Part 160 with the exception that the test agent stability information, synthesis, and purity analysis, composition and other characteristics of the test product remain with the sponsor.

Study Director

4-17-01

Date

Study Sponsor

4-25-01

Date

Study Submitter

6-20-01

Date



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Quality Assurance Statement

Study Number: GR 1683

Protocol Number: 2248

Sponsor Name: Enviro Tech Chemical Services Inc.

Type of Study: Food Contact Sanitizer Test

Audit Dates

Audits were conducted on the following dates.

Procedure	04/10/01
Facilities	04/10/01
Data	04/10/01
Report	04/10/01

Findings

Any findings were communicated to the individuals listed below and to the appropriate personnel involved with the study in a timely fashion.

Findings Reported to

04/10/01

Niranjan C. Patel, M.S.
Study Director

04/10/01

Daniel L. Prince, Ph.D.
Management

Ivan Strande

Ivan Strande
Quality Assurance

4/18/01
Date



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Study Personnel

Testing Facility Management:

Daniel L. Prince, Ph.D.
President

Study Director, Supervisory and
Laboratory Personnel

Niranjana C. Patel, M.S.
General Laboratory Manager



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1 Purpose

To determine whether or not BioSide HS 15% kills 99.999% of *Staphylococcus aureus* and *Escherichia coli* within 30 seconds in a suspension test.

2 Test System

Staphylococcus aureus; GBL-NC Stock # 202; ATCC # 6538
Escherichia coli; GBL-NC Stock # 198; ATCC # 11229

3 Disinfectant Tested: BioSide HS 15%

4 Test Conditions

- 4.1 Contact Time: 30 seconds and 60 seconds
- 4.2 Organic Soil: none
- 4.3 Test Concentration: 1 ounce/16.4 gallons (1:2099.2)
- 4.4 Test Dilution: 1 mL Test Material + 2098.2 mL Diluent
- 4.5 Diluent: 400 ppm AOAC synthetic hard water
- 4.6 Test Temperature: 20 ± 0.2C.

5 Preparation of Culture: Organisms were prepared according to the AOAC.

6 Method

99 mL of the diluted test material prepared as in section 4.4 was aliquoted into each of two wide-mouth erlenmeyer flasks. The flasks were allowed to equilibrate for ≥ 20 minutes in a 20C water bath. In parallel, two flasks were prepared as numbers controls wherein sterile phosphate buffer dilution water was substituted for the 99 mL of test material.

The efficacy assay was performed by adding 1 mL of the appropriate test system organism to the 99 mL flask as per AOAC 960.09(H). The number of bacteria present in the erlenmeyer flasks was determined after the 30 seconds and 60 seconds contact time. Ten-fold serial dilutions were made into 9 mL GBL STAT Broth (GBL STAT Broth = Trypticase Soy Broth containing 4% Tween 20 and 0.5% Azolectin) and pour plates were performed in quadruplicate using Tryptone Glucose Extract Agar (TGEA) containing neutralizer. Incubation was for 48 hours at 37 ± 1C. The colony forming units were counted using a Quebec colony counter.

The numbers control was performed by adding 1 mL of the appropriate test system organism to duplicate wide-mouth erlenmeyer flasks containing 99 mL of the sterile phosphate buffer dilution water as per AOAC 960.09 (H). The number of bacteria present in the erlenmeyer flasks was determined after ≤ 30 seconds. Ten-fold serial dilutions were made into 9 mL GBL STAT Broth. Pour plates were performed in quadruplicate were performed using TGEA. Incubation was for 48 hours at 37 ± 1C. The colony forming units were counted using a Quebec colony counter.

7. Sterility Controls



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For neutralizer broth, AOAC hard water and Phosphate buffer dilution water, 1.0 mL of each was individually plated into sterile petri dishes and the plates were poured with TGEA. The plates were incubated at 37 ± 1 C for 48 ± 8 hours. The colony forming units were counted using Quebec colony counter.

8. Confirmation of Surviving Organisms

After counting the plates, colonies of the surviving organisms, if any, were selected and subcultured onto respective agar plates and incubated at 37 ± 1 C for 24 to 48 hours to confirm the typical growth.

9 Media and Reagents

- 9.1 Nutrient Agar A, Lot # C-19
- 9.2 Nutrient Agar B, Lot # C-18
- 9.3 Phosphate Buffer Stock Solution, Lot # C-496
- 9.4 Phosphate Buffer Dilution Water, Lot # C-504
- 9.5 Tryptone Glucose Extract Agar (TGEA), Lot # C-17
- 9.6 GBL STAT Broth, (Trypticase Soy Broth containing 4.0% Tween 20 and 0.5% Azolectin), Lot # C-71
- 9.7 AOAC Hard Water, Lot # C-508, C-509, C-510

10 Additional Information

- 10.1 Purchase Order #:** 65614
- Sponsor #:** (1124)
- Enviro Tech Chemical Services
- 213 Primo Way
- Modesto, CA 95358
- Attn:** Mike Harvey
- Tel #:** 209/581-9576
- Fax #:** 209/581-9653
- GBL Reference #:** 408-33-2843, 409-33-2851
- GBL-NJ Sample #:** 27573/1-3.262
- GBL-NC Sample #:** C4664/1-3
- Study Initiation:** 03/12/01
- Date Received:** 03/07/01
- Date Tested:** 03/28/01
- Date Completed:** 03/30/01
- Protocol No.:** 2248



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10.2 Description of Test Material

Three white plastic bottles with white plastic screw caps approximately 6" x 2" containing approximately 500 mL of a clear liquid.

27573/1 = Lot # 01201; Manufacturing date: 12/01/01

27573/2 = Lot # 01221; Manufacturing date: 12/21/01

27573/3 = Lot # 10110; Manufacturing date: 01/10/01

10.3 Statistical Method: None. Basic arithmetic was used.

10.4 Records to be Maintained: The test findings reflected in this experiment will be kept on file for a period of at least five years in the Gibraltar Laboratories archives. Specific records to be maintained include a copy of this report, all raw data, sample information as provided by sponsor, and the findings of the QAU.

10.5 Other Remarks Pertaining To The Test Material

10.5.1 Chemical Nature and Concentration: Hydrogen peroxide/ peroxyacetic acid compound

10.5.2 Expiration Date: Not known by Gibraltar.

10.5.3 Storage Conditions: The test materials were stored at ambient room temperature at the testing facility.

10.5.4 Stability under above Conditions: Stability and purity are the responsibility of the sponsor.

10.5.5 Sample Retention: After all studies are complete the remaining test material, if any, will be discarded or destroyed in accordance with GBL policy and State and Federal regulations.

10.6 Archive Location: Gibraltar Laboratories, 122 Fairfield Road, Room 203A, Fairfield, New Jersey 07004-2405; or Guarantee Records Management, 215 Coles Street, Jersey City, New Jersey 07307.

10.7 Changes from the Approved Protocol: The protocol has a typographical error in the footer section for the Study Number. The correct Study No. is GR1683 not GR16883.

10.8 Circumstances: No circumstances arose during the course of this study which compromised the quality or integrity of the data reported herein.



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Table 1: Results of *Staphylococcus aureus*

	Lot # 01201		Lot # 01221		Lot # 10110	
	Cfu	Log ₁₀	Cfu	Log ₁₀	Cfu	Log ₁₀
Numbers Control	7.9 x 10 ⁷	7.90	7.9 x 10 ⁷	7.90	7.9 x 10 ⁷	7.90
30 Seconds	5.0 x 10 ²	2.70	5.2 x 10 ²	2.72	3.71 x 10 ²	2.57
60 Seconds	<10	0	<10	0	<10	0
Log Reduction in 30 Seconds	5.20		5.18		5.33	

Table 2: Results of *Escherichia coli*

	Lot # 01201		Lot # 01221		Lot # 10110	
	Cfu	Log ₁₀	Cfu	Log ₁₀	Cfu	Log ₁₀
Numbers Control	8.19 x 10 ⁷	7.91	8.19 x 10 ⁷	7.91	8.19 x 10 ⁷	7.91
30 Seconds	<10	0	<10	0	<10	0
60 Seconds	<10	0	<10	0	<10	0
Log Reduction in 30 Seconds	≥ 7.91		≥ 7.91		≥ 7.91	

Cfu = Colony Forming Units

Conclusion

BioSide HS 15%, Lot # 01201, 01221 and 10110, killed > 99.999% of *Staphylococcus aureus* and *Escherichia coli* within 30 seconds when diluted 1:2099.2 in 400 ppm AOAC hard water.

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