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REPORT No.

G-37462
03/28/01

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Page 1 of 10

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Study Title

AOAC Broad Spectrum Use-Dilution Test on BioSide HS 15%

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 26, 2001

Testing Facility

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

Laboratory Project Number (Study File)

GBL Study # GR 1684



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Page 2 of 10

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Statement Of Data Confidentiality Claims*

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
Company Agent MIKE HARVEY Date 4-20-01
Title President Signature Michael Harvey

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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Page 3 of 10

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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 1684

Protocol No.: 2249

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

Date

4-17-01

Study Sponsor

Date

4-20-01

Study Submitter

Date

6-20-01



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Page 4 of 10

LABORATORY REPORT

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Contents

Title Page 1
Confidentiality Statement 2
GLP Compliance Statement 3
Table of Contents 4
Study Personnel 5
Quality Assurance Statement 6
Purpose, Test System, Method 7
Additional Information 8
Results
Conclusion 10
Table 1 10

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Page 5 of 10

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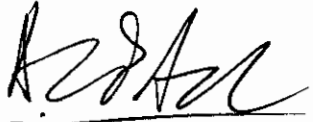
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Study Personnel

Testing Facility Management:


Daniel L. Prince, Ph.D.
President

Study Director and Supervisory
Personnel


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

Laboratory Personnel:


Niranjan C. Patel, M.S.
Microbiologist


Cezanne Vielkanowitz
Microbiologist



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Page 6 of 10

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Quality Assurance Statement

Study Number: GR 1684

Protocol Number: 2249

Sponsor Name: Enviro Tech Chemical Services

Type of Study: AOAC Use-Dilution Test

Audit Dates

Audits were conducted on the following dates.

Procedure	04/02/01
Facilities	04/02/01
Data	04/02/01
Report	04/02/01

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

04/02/01
Niranjan C. Patel, M.S.
Study Director

04/02/01
Daniel L. Prince, Ph.D.
Management

Ivan Strande
Ivan Strande
Quality Assurance

4/18/01
Date



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Page 7 of 10

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1 Purpose

To determine the antimicrobial properties of the test material using a dried organism on stainless steel carrier model (EPA).

2 Test Systems

2.1 *Staphylococcus aureus*; GBL-NC Stock # 202; ATCC # 6538

2.2 *Salmonella choleraesuis*; GBL-NC Stock # 201; ATCC # 10708

The identity and purity of these organisms were confirmed by streaking onto selective agars and observing for characteristic morphological appearance.

3 Disinfectant Tested: BioSide HS 15%

4 Dilution Tested: 1:1280 (example: 1 mL test material + 1279 mL diluent)

Diluent: sterile 400 ppm AOAC synthetic hard water

5 Carriers: The stainless steel penicylinders (8 ± 1 mm o.d. x 6 ± 1 mm i.d. x 10 ± 1 mm length) were stored in 1N NaOH for 24 hours. The penicylinders were then washed with tap water and then deionized water and sterilized at 121C and 15 psi for 20 minutes in 0.1% asparagine.

6 Growth Medium: Anatone Nutrient Broth Medium [AOAC section 6.1.01(a)] for preparation of organisms.

7 Subculture Media (Recovery Broth): Lethen Broth [AOAC section 6.1.01(d)(3)], 10 mL in 20 mm x 100 mm test tubes for subculture recovery from each medicated carrier.

8 Culture: 48 hours, Anatone Nutrient Broth at 37 ± 1C representing transfers originally derived from at least 4 but ≤ 30 consecutive 24-hour serial subcultures from nutrient agar slant stock.

Organic Load in Culture: 5% horse serum in the inoculum.

9 Contamination: The carriers were soaked for 15 minutes in 20 mL of the appropriate test system culture broth. The carriers were then transferred onto two layers of Whatman No. 2 filter paper in a sterile petri dish and allowed to dry at 37 ± 1C for 40 minutes.



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Page 8 of 10

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10 Disinfection: Using a sterile wire hook, each contaminated and dried carrier was transferred, at 30-second staggered intervals, into separate 25 x 150 mm test tubes containing 10 mL of disinfectant each. The carriers remained in the disinfectant tubes for 10 minutes, during which time the required disinfectant temperature of $20 \pm 0.2C$ was maintained by a water bath.

11 Subculture: Following contact with the disinfectant, the medicated carriers were transferred (by sterile wire hook), at 30-second staggered intervals, into test tubes containing 10 mL of recovery broth (Section 7).

12 Incubation and Neutralization: The recovery broth tubes were incubated for 48 hours at $37 \pm 1C$. The recovery broth tubes were visually observed for gross turbidity and for typical growth. The recovery broth tubes having no growth were inoculated with approximately 10 to 100 cfu of the respective challenge organism to verify neutralization.

13 Population Verification (Numbers Control): To confirm that at least 10^4 cfu were present on each carrier, two additional contaminated and dried carriers were sonicated in the recovery broth for 15 minutes to dislodge the adhering organisms. This was diluted to 10^{-5} , and then 1.0 mL aliquots were plated into Trypticase Soy Agar (TSA) and the plates were incubated for 48 hours at $37 \pm 1C$. The colony counts were extrapolated to cfu per carrier.

14 Viability Control: Two contaminated and dried carriers per organism tested were directly transferred into recovery broth (no disinfection treatment) and incubated for 48 hours at $37 \pm 1C$.

15 Media and Reagents

Anatone Broth Lot # A-24; Lethen Broth Lot # C-38; Trypticase Soy Agar (TSA) Lot # C-30; Horse Serum Lot # 67H4610; 0.1% Asparagine Lot # B-6; 400 ppm AOAC synthetic hard water Lot # C-501, C-506.

16 Additional Information

16.1 Purchase Order #: 65614

Sponsor #: (1124)

Enviro Tech Chemical Services Inc.

213 Primo Way

Modesto, CA 95358



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Page 9 of 10

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Attn: Mike Harvey
Tel #: 209/581-9576
Fax #: 209/581-9653

16.2 GBL Reference #: 400-33-2777, 402-33-2798
GBL-NJ Sample #: 27561/1-2.12
GBL-NC Sample #: C4665/1-2
Study Initiation: 03/12/01
Date Received: 03/07/01
Date Tested: 03/19/01
Date Completed: 03/26/01

16.3 Statistical Method: None. Basic arithmetic was used.

16.4 Description of Test Material

Two white plastic bottles with white plastic screw caps approximately 8" x 2" each containing approximately 500 mL of a clear liquid.

27561/1 - Lot # 01201, Manufacturing date: 12/01/00
27561/2 - Lot # 01221, Manufacturing date: 12/21/00

16.5 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.

16.6 Other Remarks Pertaining To The Test Material

16.6.1 Chemical Nature and Concentration: Hydrogen Peroxide and Peroxyacetic acid.

16.6.2 Expiration Date: Not known by Gibraltar

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

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

16.6.5 Sample Retention: The remaining test material will be used for additional studies and will be 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.



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Page 10 of 10

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16.7 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.

16.8 Changes from the Approved Protocol: None.

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

Table 1: BioSide HS 15% Efficacy Results

Lot #	<i>Staphylococcus aureus</i>		<i>Salmonella Choleraesuis</i>	
	# Positive /# Tested	Neutralization Challenge	# Positive /# Tested	Neutralization Challenge
01201	0/60	60/60	0/60	60/60
01221	0/60	60/60	0/60	60/60
Numbers Control*	1.3 x 10 ⁵		5.2 x 10 ⁴	
	1.4 x 10 ⁵		3.7 x 10 ⁴	
	3.9 x 10 ⁵		3.4 x 10 ⁴	
Neutralization Challenge Inoculum	20 cfu		20 cfu	
Viability Control	+, +		+, +	

+ = typical growth

* = average of two carriers

cfu = colony forming units

Conclusion

BioSide HS 15%, lots 01201 and 01221, when diluted 1:1280 in 400 ppm AOAC synthetic hard water in the presence of 5% organic load, passed the AOAC Use-Dilution Test in ten minutes against *Staphylococcus aureus* and *Salmonella choleraesuis*.

102/10 gal