

Volume _____

FINAL REPORT

AOAC USE DILUTION TEST Healthcare

Test Agent: Easy DECON™

Data Requirements
EPA Guidelines 810.2100 (c), (d), (e)

Author
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Study Completion Date
June 8, 2004

Performing Laboratory
MICROBIOTEST, INC.
105B Carpenter Drive
Sterling, Virginia 20164

Laboratory Project Identification Number
479-114

Submitted to: ENVIROFOAM TECHNOLOGIES, INC.
2903 Wall Triana Hwy. , Suite 5B
Huntsville, AL 35824

STATEMENT OF NO DATA CONFIDENTIALITY

Title: AOAC Use Dilution Test – Healthcare

Performed by: MICROBIOTEST, INC.
105B Carpenter Drive
Sterling, Virginia 20164

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 Agent _____

_____ Date

COMPLIANCE STATEMENT

This study meets the requirements for 40 CFR § 160 with the following exceptions:

- Information on the identity, strength, purity, stability, uniformity, and dose solution analysis of the test agent resides with the sponsor of the study.

The following technical personnel participated in this study:

Temitope O. Odebunmi, Emily B. Robbins, M. Hamid Bashir, Angela L. Hollingsworth, Rita M. Peralta

Study Director: MICROBIOTEST, INC.

_____	_____
Temitope O. Odebunmi	Date

Submitted by:

_____	_____
Name	Title
_____	_____
Signature	Date

Sponsor: ENVIROFOAM TECHNOLOGIES, INC.

_____	_____
Name	Title
_____	_____
Signature	Date

QUALITY ASSURANCE UNIT STATEMENT

Title: AOAC Use Dilution Test - Healthcare

The Quality Assurance Unit of MICROBIOTEST has inspected Project Number 479-114 in compliance with current Good Laboratory Practice regulations, (40 CFR § 160).

The dates that inspections were made and the dates that findings were reported to management and to the study director are listed below.

<u>PHASE INSPECTED</u>	<u>DATE OF INSPECTION</u>	<u>DATE REPORTED TO STUDY DIRECTOR</u>	<u>DATE REPORTED TO MANAGEMENT</u>
Protocol	05/25/04	05/27/04	06/07/04
In Process	05/25/04	05/27/04	06/07/04
Final Report	06/07/04	06/07/04	06/08/04

Nathan S. Jones, RQAP-GLP
Quality Assurance Unit

Date

TABLE OF CONTENTS

FINAL REPORT - COVER PAGE	1
STATEMENT OF NO DATA CONFIDENTIALITY	2
COMPLIANCE STATEMENT	3
QUALITY ASSURANCE UNIT STATEMENT	4
TABLE OF CONTENTS	5
TEST SUMMARY	6
TEST CONDITIONS	7
STUDY DATES AND FACILITIES	8
RECORDS TO BE MAINTAINED	8
RESULTS	8 - 9
CONCLUSIONS	9
APPENDIX I	
APPENDIX II	

TEST SUMMARY

TITLE: AOAC Use Dilution Test - Healthcare

STUDY DESIGN: This study was performed according to the signed protocol and project sheets issued by the Study Director.

See Project Sheets (Appendix I)

See signed protocol (Appendix II)

TEST MATERIALS SUPPLIED BY THE SPONSOR OF THE STUDY:

To prepare Easy DECON™ – Batch No. 1

1. Penetrator, Lot No. 03-439, received at MICROBIOTEST, INC. on 05/18/04, and assigned DS No. 6706.
2. Fortifier, Lot No. 5403A, received at MICROBIOTEST, INC. on 05/18/04 and assigned DS No. 6706.
3. Booster, Lot No. 11403B, received at MICROBIOTEST, INC. on 05/18/04 and assigned DS No. 6706.

To prepare Easy DECON™ – Batch No. 2

4. Penetrator, Lot No. 03-425 (at least 60 days aged), received at MICROBIOTEST, INC. 05/18/04, and assigned DS No. 6705.
5. Fortifier, Lot No. 10903A (at least 60 days aged), received at MICROBIOTEST, INC. on 05/18/04 and assigned DS No. 6705.
6. Booster, Lot No. 11403A (at least 60 days aged), received at MICROBIOTEST, INC. on 05/18/04 and assigned DS No. 6705.

SPONSOR: ENVIROFOAM TECHNOLOGIES, INC.
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MICROBIOTEST, INC.

TEST CONDITIONS

Challenge microorganisms (adjusted to yield carrier counts between 1.0×10^4 – 2.0×10^6 colony forming units /carrier):

Staphylococcus aureus, ATCC 6538

Pseudomonas aeruginosa, ATCC 15442

Salmonella choleraesuis, ATCC 10708

Active ingredient in test product:

Quaternary Ammonium Compound & Hydrogen Peroxide

Neutralizer used:

D/E Broth

Contact time:

10 Minutes

Contact temperature:

22±1C (23C)

Test agent activation:

To prepare Easy DECON™, 49% by weight Fortifier was combined with 2% by weight Booster and mixed for 1-2 minutes. The Fortified Blend was combined with 49% by weight Penetrator and mixed.

Media and reagents:

Nutrient Agar

Nutrient Broth

Asparagine solution, 0.1%

Sodium hydroxide solution, 1N

D/E Broth

Phosphate Buffered Saline

Phosphate Buffered Saline containing 1% Polysorbate 80

Tryptic Soy Agar

Gram Stain Reagents

STUDY DATES AND FACILITIES

MICROBIOTEST, INC.

The laboratory phase of this test was performed at MICROBIOTEST, INC., 105B Carpenter Drive, Sterling, VA 20164, from 05/25/04 to 05/28/04. The study director signed the protocol on 05/24/04. The study completion date is the date the study director signed the final report.

All changes or revisions of the protocol were documented, signed by the study director, dated and maintained with the protocol.

RECORDS TO BE MAINTAINED

All testing data, protocol, protocol modifications, test material records, the final report, and correspondence between MICROBIOTEST and the sponsor will be stored in the archives at MICROBIOTEST, INC., 105B Carpenter Drive, Sterling, VA 20164, or at a controlled facility off site.

RESULTS

Results are presented in Tables 1 and 2. The challenge microorganisms were confirmed by Gram stain and colony morphology to be consistent with *S. aureus*, *P. aeruginosa*, and *S. choleraesuis*. The sterility control exhibited no growth. The viability and neutralizer effectiveness controls exhibited growth. An average of 97 colony-forming units (CFU)/tube of *S. aureus*, 50 CFU/tube of *P. aeruginosa*, and 72 CFU/tube of *S. choleraesuis* were added to the neutralizer effectiveness controls. Bacteriostasis streaks exhibited no growth.

Table 1

Test Results

Results Expressed as Number of Tubes Exhibiting Growth / Total Number of Tubes

Microorganism	Easy DECON™ Batch No. 1	Easy DECON™ Batch No. 2
<i>S. aureus</i>	0/60	0/60
<i>P. aeruginosa</i>	0/60	0/60
<i>S. choleraesuis</i>	0/60	0/60

RESULTS (continued)

MICROBIOTEST, INC.

Table 2

Carrier Counts

Results Expressed as Average Colony Forming Units (CFU) per Carrier

Microorganism	Avg. CFU/carrier
<i>S. aureus</i>	7.1×10^4
<i>P. aeruginosa</i>	4.1×10^5
<i>S. choleraesuis</i>	3.3×10^4

CONCLUSION

When tested as described, Easy DECON™ passed the AOAC Use Dilution Test-Healthcare when *S. aureus*, *P. aeruginosa*, and *S. choleraesuis* were exposed to the test agent for 10 minutes at 22±1C. All of the controls met the criteria established for a valid test. These conclusions are based on observed data.