

Volume _____

FINAL REPORT
AOAC TUBERCULOCIDAL ACTIVITY OF
DISINFECTANTS

Test Agent: Easy Decon[®] 200-531X

Data Requirements
EPA Guidelines 810.2100 (h)

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Study Completion Date
March 14, 2008

Performing Laboratory
MICROBIOTEST
105 Carpenter Drive
Sterling, Virginia 20164

Laboratory Project Identification Number
634-103

Submitted to: EFT Holdings, Inc.
1012 Oster Drive, Suite A
Huntsville, AL 35816

STATEMENT OF NO DATA CONFIDENTIALITY

Title: AOAC Tuberculocidal Activity of Disinfectants

Performed by: MICROBIOTEST
105 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

QUALITY ASSURANCE UNIT STATEMENT

Title of Study: AOAC Tuberculocidal Activity of Disinfectants

The Quality Assurance Unit of MICROBIOTEST has inspected Project Number 634-103 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	11/27/07	11/27/07	03/14/08
In Process	11/27/07	11/27/07	03/14/08
Final Report	03/05/08	03/05/08	03/14/08

Nathan S. Jones, RQAP-GLP
Manager, Quality Assurance Unit

Date

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TEST SUMMARY

TITLE: AOAC Tuberculocidal Activity of Disinfectants

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:

1. Easy Decon[®] 200-531X components: EFT DF 200 Penetrator, EFT DF 200 Fortifier, EFT DF 200 Fortifier Booster; Lot No. T-1001, received at MICROBIOTEST 11/12/07, and assigned DS No. 9030.
2. Easy Decon[®] 200-531X components: EFT DF 200 Penetrator, EFT DF 200 Fortifier, EFT DF 200 Fortifier Booster; Lot No. T-1002, received at MICROBIOTEST 11/12/07, and assigned DS No. 9031.

SPONSOR : EFT Holdings, Inc.
1012 Oster Drive, Suite A
Huntsville, AL 35816

TEST CONDITIONS

Challenge microorganism:

Mycobacterium bovis, BCG; Organon Teknika Corp.

Active ingredient in test product:

Hydrogen Peroxide and Benzyl - C12 - C16 Alkyl Di-Methyl Chloride

Neutralizer used:

D/E Neutralizing Broth

Contact time:

10 Minutes

Contact temperature:

Ambient Room Temperature (22C)

Test material preparation:

Penetrator (49% wt.) + Fortifier (49% wt.) + Fortifier Booster (2% wt.)
The product was dispensed and used immediately after mixing.

Serum:

Heat-inactivated horse serum was added to the inoculum for a final concentration of 5% organic load.

Carriers:

Porcelain penicylinders

Media and reagents:

Middlebrook 7H9 broth (7H9)
Middlebrook 7H11 agar
Kirchner medium (KM)
Modified Proskauer-Beck Medium (MPBM)
D/E Neutralizing Broth
Phosphate Buffered Saline

TEST CONDITIONS (continued)

Media and reagents (continued):

Phosphate Buffered Saline containing 1% Polysorbate 80
Saline solution
Heat-inactivated horse serum
Acid-fast stain reagents

STUDY DATES AND FACILITIES

The laboratory phase of this test was performed at MICROBIOTEST, 105 Carpenter Drive, Sterling, VA 20164, from 11/27/07 to 02/25/08. The study director signed the protocol on 11/27/07. 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, 105 Carpenter Drive, Sterling, VA 20164, or at a controlled facility off site.

RESULTS

Results are presented in Tables 1 - 3. The challenge microorganism was confirmed by Acid fast stain and colony morphology to be consistent with *M. bovis*. The sterility controls exhibited no growth. The neutralizer effectiveness controls and the viability controls exhibited growth. An average of 3 CFU/mL of *M. bovis* was added to the 20 mL portions of MPBM, 7H9 and KM for the Neutralizer Effectiveness Controls.

RESULTS (continued)

Table 1

Carrier Counts

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

Challenge Microorganism	Average CFU/Carrier
<i>M. bovis</i>	5.7 x 10 ⁵

Table 2

Test Results – Lot No. Lot No. T-1001

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

Day	Media		
	MPBM	7H9	KM
60	0/10	0/10	0/10
90	0/10	0/10	0/10

Table 3

Test Results – Lot No. Lot No. T-1002

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

Day	Media		
	MPBM	7H9	KM
60	0/10	0/10	0/10
90	0/10	0/10	0/10

CONCLUSIONS

When tested as described, Easy Decon[®] 200-531X passed the AOAC Tuberculocidal Activity of Disinfectants test when *Mycobacterium bovis* BCG, containing a 5% organic load, was exposed to the test agent for 10 minutes at 22C. All of the controls met the criteria established for a valid test. These conclusions are based on observed data.