UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV - 5 2001

MEMORANDUM

SUBJECT: Transmittal of the Performance Report for AOAC Use Dilution Test of T.B. Phene 28 Day Post Preparation (EPA Reg. No. 211-36))

FROM: Susan Lawrence, Chief
Antimicrobials and Plant Pathogen Branch
Biological and Economic Analysis Division

TO: Michele Wingfield, Chief
Products Science Branch
Antimicrobials Division

Gerald Stubbs, Chief
Case Development, Policy and Enforcement Branch
Western Region/ORE

Enclosed please find the performance report of the AOAC Use Dilution Test for T.B. Phene 28 Day Post Preparation (EPA Registration Number 211-36) against *Staphylococcus aureus* and *Pseudomonas aeruginosa*. The original report and the Biological Report of Analysis (BRA) forms are provided to AD, with copies forwarded to OECA.

On July 12, 2001 the laboratory received a total of three samples of the product. Sample numbers 071201F257401-1 (lot no. 04041007), 071201F257401-4 (lot no. 06281002), and 071201F257401-7 (lot no.1228007) were tested on September 5 and 6, 2001 for efficacy against *Staphylococcus aureus* and *Pseudomonas aeruginosa* respectively. The product samples do not have an expiration date.

The performance results for T.B. Phene 28 day Post Preparation against *Staphylococcus aureus* indicate that the product is **effective** for sample numbers 071201F257401-1 and 71201F257401-4 and **ineffective** for sample no. 071201F257401-7 when tested by the AOAC Use Dilution Test with a 10 minute contact time at 20°C. Sample no. 071201F257401-7 exhibited positive growth in 2 of 60 carriers challenged. The two positive tubes were confirmed to be the test microbe, *Staphylococcus aureus*.

The performance results for T.B. Phene 28 day Post Preparation against *Pseudomonas aeruginosa* indicate that the product is **ineffective** for sample numbers 071201F257401-1 and 71201F257401-4 and **effective** for sample number 071201F257401-7 when tested by the AOAC Use Dilution Test with a 10 minute contact time at 20°C. Sample number 071201F257401-1 exhibited positive growth in 2 of 60 carriers challenged and sample number 71201F257401-4

CONCURRENCES

SYMBOL	7503C	7503C						
SURNAME	Linda C.	Lawrence						
DATE	11.8.01	11.5.01						

Phenol resistance testing was not conducted in keeping with the Agency's decision to drop this requirement. An adequate challenge inoculum level was achieved. The formulation chemistry analyses will be forwarded under separate cover by the Analytical Chemistry Branch/BEAD within the next several weeks. The tuberculocidal assessment for this product immediately following preparation of the use dilution is in the incubation phase; 90 day results will be read the first week in January 2002.

Please contact Stephen Tomasino, Team Leader, OPP Microbiology Laboratory, at 410-305-2976 if there are any questions about this report.

Enclosures:

cc: Stephen Tomasino (memo only)
Michael Hardy (memo only)
Kate Bouve (memo only)

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

BIOLOGICAL REPORT OF ANALYSIS

1. SAMPLE NO. 071201F257401-1
2. DATE COLLECTED 07/12/01
3. REGION VII

SAMPLE IDENTIFICATION

4. LOT OR CODE NO(S).	5. EPA REGISTRATION NO.	6. ESTABLISHMENT NO.
04041007	211-36	211-KS-1

7. PRODUCT NAME
T.B. Phene (tested 28 days post-preparation)

8. PRODUCER NAME AND ADDRESS *(Include ZIP code)*
Central Solutions
P.O. Box 15276
3130 Brinkerhoff Road
Kansas City, Kansas 66115

9. DEALER NAME AND ADDRESS *(Include ZIP code)*

10. PHYSICAL FORM		EMULS. CONC.		PRESSURE SPRAY		DUST		GRANULAR
		WET. POWDER		AEROSOL		BAIT	X	OTHER

11. INGREDIENTS

Active Ingredients:
Sodium ortho-benzyl-para-chlorophenate.....4.40%
Sodium ortho-phenylphenate.....2.82%
Sodium para-tertiary-amylphenate.....2.49%
Inert Ingredients.....90.29%

TEST

12. TYPE OF TEST	13. TEST ORGANISM(S)		
AOAC Use-Dilution	*Staphylococcus aureus* (ATCC 6538) *Pseudomonas aeruginosa* (ATCC 15442) Organic Soil- 5% (Fetal bovine serum)	14. METHOD NO.	955.15
		15. DURATION	10 minutes
		16. CONCENTRATION	1:128 *
		17. DILUENT	Sterile DI** Water

18. SUMMARY

T.B. Phene (EPA Reg. No. 211-36) Sample Number 071201F257401-1, Lot Number 04041007 was effective when tested by the AOAC Use-Dilution Method against *Staphylococcus aureus*. There were no positive carriers out of 60 carriers challenged. T.B. Phene Sample Number 071201F257401-1, Lot Number 04041007 was **Not Effective** when tested by the AOAC Use-Dilution Method against *Pseudomonas aeruginosa*. There were two positive carriers out of 60 carriers challenged. The positive tubes were confirmed to be *Pseudomonas aeruginosa*.

* Tested 28 days post-preparation, **De-ionized

19. RESULTS

Test Date: 09/05/01 Test Organism: *Staphylococcus aureus*
Number of carriers with growth: 0
Number of carriers without growth: 60
Total number of carriers: 60

Test Date: 09/06/01 Test Organisms: *Pseudomonas aeruginosa*
Number of carriers with growth: 2
Number of carriers without growth: 58
Total number of carriers: 60

20. TESTER'S INITIALS	21. SIGNATURE OF LAB SUPERVISOR	22. LABORATORY	23. DATE
[illegible]	Susan M. Lawrence	OPP Microbiology Lab	11/05/01

EPA Hq Form 8510-14 (10-76) LABORATORY COPY

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

BIOLOGICAL REPORT OF ANALYSIS

1. SAMPLE NO. 071201F257401-4
2. DATE COLLECTED 07/12/01
3. REGION VII

SAMPLE IDENTIFICATION

4. LOT OR CODE NO(S).	5. EPA REGISTRATION NO.	6. ESTABLISHMENT NO.
06281002	211-36	211-KS-1

7. PRODUCT NAME
T.B. Phene (tested 28 days post preparation)

8. PRODUCER NAME AND ADDRESS *(Include ZIP code)*
Central Solutions
P.O. Box 15276
3130 Brinkerhoff Road
Kansas City, Kansas 66115

9. DEALER NAME AND ADDRESS *(Include ZIP code)*

10. PHYSICAL FORM		EMULS. CONC.		PRESSURE SPRAY		DUST		GRANULAR
		WET. POWDER		AEROSOL		BAIT	X	OTHER

11. INGREDIENTS

Active Ingredients:
Sodium ortho-benzyl-para-chlorophenate.....4.40%
Sodium ortho-phenylphenate.....2.82%
Sodium para-tertiary-amylphenate.....2.49%
Inert Ingredients.....90.29%

12. TYPE OF TEST	13. TEST ORGANISM(		
AOAC Use-Dilution	*Staphylococcus aur*	14. METHOD NO.	955.15
	Pseudomonas aerugi	15. DURATION	10 minutes
	Organic Soil- 5% (	16. CONCENTRATION	1:128 *
		17. DILUENT	Sterile DI** Water

18. SUMMARY

T.B. Phene (EPA Reg. No. 211-36) Sample N s effective when tested by the AOAC Use-Dilution Method against S carriers out of 60 carriers challenged. T.B. Phene Sample N s **Not Effective** when tested by the AOAC Use-Dilution Method ag ee positive carriers out of 60 carriers challenged. Then positive nosa.

* Tested 28 days post-preparation, ** De-

19. RESULTS

Test Date: 09/05/01 Test Organism: *Sta*
Number of carriers with growth: 0
Number of carriers without growth: 60
Total number of carriers: 60

Test Date: 09/06/01 Test Organisms: *Pse*
Number of carriers with growth: 3
Number of carriers without growth: 58
Total number of carriers: 60

← error 58 should be 57.

20. TESTER'S INITIALS	21. SIGNATURE OF LAB SUPERVISOR	22. LABORATORY	23. DATE
	Susan H Lawrence	OPP Microbiology LAB	11/05/01

EPA Hq Form 8510-14 (10-76) LABORATORY COPY

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

BIOLOGICAL REPORT OF ANALYSIS

1. SAMPLE NO. 071201F257401-7
2. DATE COLLECTED 07/12/01
3. REGION VII

SAMPLE IDENTIFICATION

4. LOT OR CODE NO(S).	5. EPA REGISTRATION NO.	6. ESTABLISHMENT NO.
1228007	211-36	211-KS-1

7. PRODUCT NAME
T.B. Phene (tested 28 days post-preparation)

8. PRODUCER NAME AND ADDRESS *(Include ZIP code)*
Central Solutions
P.O. Box 15276
3130 Brinkerhoff Road
Kansas City, Kansas 66115

9. DEALER NAME AND ADDRESS *(Include ZIP code)*

10. PHYSICAL FORM		EMULS. CONC.		PRESSURE SPRAY		DUST		GRANULAR
		WET. POWDER		AEROSOL		BAIT	X	OTHER

11. INGREDIENTS

Active Ingredients:
Sodium ortho-benzyl-para-chlorophenate.....4.40%
Sodium ortho-phenylphenate.....2.82%
Sodium para-tertiary-amylphenate.....2.49%
Inert Ingredients.....90.29%

TEST

12. TYPE OF TEST	13. TEST ORGANISM(S)	14. METHOD NO.	955.15
AOAC Use-Dilution	*Staphylococcus aureus* (ATCC 6538) *Pseudomonas aeruginosa* (ATCC 15448) Organic Soil- 5% (Fetal bovine serum)	15. DURATION	10 minutes
		16. CONCENTRATION	1:128 *
		17. DILUENT	Sterile DI** Water

18. SUMMARY

T.B. Phene (EPA Reg. No. 211-36) Sample Number 071201F257401-7, Lot Number 1228007 was **Not Effective** when tested by the AOAC Use-Dilution Method against *Staphylococcus aureus*. There were two positive carriers out of 60 carriers challenged. T.B. Phene Sample Number 071201F257401-7, Lot Number 1228007 was effective when tested by the AOAC Use-Dilution Method against *Pseudomonas aeruginosa*. There was one positive carrier out of 60 carriers challenged. The positive tubes were confirmed to be the test microbe.

* Tested 28 days post-preparation, ** De-ionized

19. RESULTS

Test Date: 09/05/01 Test Organism: *Staphylococcus aureus*
Number of carriers with growth: 2
Number of carriers without growth: 58
Total number of carriers: 60

Test Date: 09/06/01 Test Organisms: *Pseudomonas aeruginosa*
Number of carriers with growth: 1
Number of carriers without growth: 59
Total number of carriers: 60

20. TESTER'S INITIALS	21. SIGNATURE OF LAB SUPERVISOR	22. LABORATORY	23. DATE
MS (M) mcKr	Susan M Lawrence	OPP Microbiology LAB	11/05/01

EPA Hq Form 8510-14 (10-76) LABORATORY COPY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OPPTS/OPP/BEAD/APRB

This performance report has been reviewed by:

Cynthia D. Szymanski, Quality Assurance Officer

Signature: Cynthia D. Szymanski Date: 10/22/01

Title of Performance Report:

Performance Report for the AOAC Use Dilution Test of T.B. Phene, 28 Day Post-Preparation (E.P.A. Reg. No. 211-36)

Performance Report for:

Sample No. 071201F257401-1 (Lot No. 04041007) Test Date: 9/5/01 (Tested against *Staphylococcus aureus*)
Sample No. 071201F257401-4 (Lot No. 06281002) Test Date: 9/5/01 (Tested against *Staphylococcus aureus*)
Sample No. 071201F257401-7 (Lot No. 1228007) Test Date: 9/5/01 (Tested against *Staphylococcus aureus*)

Sample No. 071201F257401-1 (Lot No. 04041007) Test Date: 9/6/01 (Tested against *Pseudomonas aeruginosa*)
Sample No. 071201F257401-4 (Lot No. 06281002) Test Date: 9/6/01(Tested against *Pseudomonas aeruginosa*))
Sample No. 071201F257401-7 (Lot No. 1228007) Test Date: 9/6/01 (Tested against *Pseudomonas aeruginosa*)

Comments: None

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

TITLE OF DISINFECTANT PERFORMANCE REPORT:

Performance Report for the AOAC Use-Dilution Test of T.B. Phene 28 Day Post-Preparation (EPA Reg. No. 211-36)

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U.S. Environmental Protection Agency
OPP Microbiology Laboratory

Protocol Number's: 2001-029 and 030

Good Laboratory Practices (GLP) Statement

AOAC Use-Dilution Test of T.B. Phene 28 Day Post Preparation
(EPA Reg. No. 211-36)

This study was conducted in accordance with Good Laboratory Practice Standards (FIFRA 40 CFR Part 160) with the following exceptions:

The test substance was not characterized (Section 160.105) by the OPP Microbiology Laboratory. The OPP Analytical Chemistry Branch is responsible for conducting the formulation chemistry verification.

The phenol resistance test as specified in Section 10.5.13 of SOP MB-05-01 was not performed. The Agency published an interim notice on November 22, 2000 and a final Pesticide Registration notice on June 19, 2001, eliminating phenol resistance testing from the efficacy tests performed on antimicrobial products.

Stephen Tomasino 9-20-01
Stephen Tomasino — Date
Study Director

Rebecca Schultheiss 9.20.01
Rebecca Schultheiss — Date
Test Coordinator

Study Protocol: OPP Microprotocol #2001-29
OPP Microbiology Laboratory

Title: Performance Evaluation of T.B. Phene Disinfectant (EPA Reg. No. 211-36) against *Staphylococcus aureus*.

Purpose: The purpose of this assay is to determine the effectiveness of an antimicrobial product against *S. aureus* on a hard surface prepared approximately 28 days prior to use. This procedure simulates the test conditions previously used to determine the product's efficacy for registration purposes. The Antimicrobials Division (AD) of EPA's Office of Pesticide Programs (OPP) concurred on the test methodology and conditions associated with this study on 08/08/01 (see attached concurrence notice and the associated paperwork).

Test Identification: AOAC Use-dilution Test (Reference: Official Methods of Analysis. 1990. 15th Ed., Association of Official Analytical Chemists, Arlington, VA, Method 955.15). Test methodology is described in the following OPP Microbiology Laboratory SOP: MB-05-02 AOAC Use Dilution Method for Testing Disinfectants.

Test Substance: T.B. Phene Disinfectant
EPA Reg. No. 211-36

Sample No. 071201F257401-1, Lot No. 04041007
Sample No. 071201F257401-4, Lot No. 06281002
Sample No. 071201F257401-7, Lot No. 1228007

Active Ingredients:
Sodium ortho-benzyl-para-chlorophenate.....4.40%
Sodium ortho-phenylphenate.....2.82%
Sodium para-tertiary amylphenate.....2.49%
Inert Ingredients.....90.29%

(Chemical Analysis and Verification will be performed by the OPP Analytical Chemistry Branch, EPA Environmental Science Center, 701 Mapes Road, Ft. Meade, MD 20755-5350.)

Formulation: Liquid

Neutralizer: Letheen Broth

Controls: Performance and Sterility Assessment of Media and Reagents, and Carrier

Counts

Sponsor: EPA Office of Pesticide Programs, Antimicrobials Division and EPA Office of Enforcement and Compliance Assurance (OECA), Agriculture and Ecosystem Division, Agricultural Branch

Test Facility: OPP Microbiology Laboratory, EPA Environmental Science Center, 701 Mapes Road, Ft. Meade, MD 20755-5350.

Proposed Experimental Start Date: 09/05/01

Proposed Experimental Completion Date: 09/07/01

Test System: The test system used in this study is in accordance to the EPA data requirements for efficacy testing of hospital disinfectants used on hard surfaces. *S. aureus* is the microbial agent administered in this study. The culture is obtained annually from the American Type Culture Collection (ATCC). Initial identification confirmation testing for quality control and the generation of the first series of stock cultures are performed concurrently. Selective media, Gram staining, and API strips or the Vitek 32 System for the automated identification of microorganisms are used for the initial and monthly identification confirmation. Generation of new stock cultures and confirmation testing are performed every 30 days. The microbial agent is assigned a Microbe Received and Microbe Expiration number (MRME). The MRME number consists of the date received (MR) and the date the reconstituted microbe expires (ME). The MRME culture notation will have a suffix; for *Staphylococcus* the suffix will be S. The notation for the test culture consists of the MRME number and notation for the monthly and daily transfer numbers. Also, TC is applied to indicate that it is a test culture. Test microbe culture maintenance and notation is described in the OPP Microbiology Laboratory SOP: MB-02-01 Test Microbes for the AOAC Use-Dilution Method, AOAC Germicidal Spray Product Test, Germicidal Towelette Product Test, and the AOAC Confirmatory Tuberculocidal Test Method: Culture Initiation, Culture Maintenance and Quality Control.

Experimental Design:

Test Microbes:	*Staphylococcus aureus*, ATCC 6538
Subculture Media:	Letheen broth
Neutralizer:	Letheen broth
Carriers:	Carriers are polished stainless steel cylinders, 8 +/- 1 mm OD, 6 +/- mm ID, 10 +/- 1mm length; type 304 stainless

steel, SS 18-8 (S & L Metal Products Corp., Maspeth, NY Carriers are physically and biologically screened prior to use. A single test involves the evaluation of 60 inoculated carriers (one organism) against one product sample. In addition to the 60 carriers, 6 carriers are required to estimate carrier bacterial load and 6 more are included as extras. Thus, a total of 72 seeded carriers are required to perform a single test.

Method: AOAC Use-dilution Test (Reference: Official Methods of Analysis. 1990. 15th Ed., Association of Official Analytical Chemists, Arlington, VA, Method 955.15). Test methodology is described in the following OPP Microbiology Laboratory SOP: MB-05-02 AOAC Use Dilution Method for Testing Disinfectants.

Culture: The test culture is initiated by inoculating a 10 mL tube (20 mm x 100 mm) of nutrient broth or synthetic broth from a stock slant culture. The test culture is serially subcultured for at least three consecutive 24±2 hour periods in 10 mL of nutrient broth or synthetic broth at 37±1°C. The test culture is subcultured once again in nutrient broth or synthetic broth and incubated at 37±1°C for 48 to 54 hours. These cultures will be used to seed carriers. The appropriate amount of organic soil is added to the pooled culture prior to carrier inoculation.

Carrier Inoculation: Using a sterile hook, carriers are aseptically transferred into tubes of the test culture. After 15 minutes of contact time with the broth culture, the carriers are removed using a sterile wire hook. The carriers are drained by tapping them against the side of the tube. Each carrier is placed on its end in a sterile glass petri dish containing a double layer of sterile Whatman No. 2 filter paper. Carriers (12) are transferred from the culture tubes to each of 6 petri dishes. Once all (72) of the carriers have been transferred, they are dried for 40 minutes in a 37±1°C incubator. The seeded carriers are used the day of preparation.

Organic Soil Load: 5% Fetal Bovine Serum

Use Dilution: 1:128 (1 part disinfectant plus 127 parts sterile DI water) Product stored at room temperature under chain of custody

for approximately 28 days (see media preparation sheet for date and time of preparation).

Application: Contact time is 10 minutes.

Subculture: After the last carrier of a set (20 carriers) has been treated with the disinfectant, and the exposure time is complete, each carrier is transferred in order, into the primary subculture tubes containing 10 mL letheen broth. A minimum of 30 minutes after the last carrier is deposited, each carrier is transferred to a secondary subculture tube containing 10 mL of the letheen broth.

Incubation: The primary and secondary subculture tubes are incubated at 37°C for 48±2 hr. A positive result is one in which the broth culture appears turbid. A negative result is one in which the broth appears clear.

Confirmation: Gram stains are performed on smears taken from selected positive culture tubes. For the additional confirmatory tests, a loopful of broth from each selected culture tube is streaked on both TSA and selective media appropriate for the test organism and incubated for 24±2 hr at 37±1°C. The selective agar is checked for the correct reaction and the culture on the TSA plate is used for preparing the inoculum for the API strips or the Vitek 32 System for the automated identification of microorganisms.

Statistics: None Required.

Data Retention: Completed forms are archived in notebooks kept in locked file cabinets adjacent to offices D217. Archived data is subject to OPP's official retention schedule contained in the OPP Microbiology Laboratory SOP ADM-01: Preparation and Review of Disinfectant Performance Reports.

A final report will be prepared. One copy of the final report will be kept in the OPP lab's Quality Assurance files. The report with original signatures will be forwarded to AD. A copy is sent to OECA.

Protocol Approval:

Study Director/Date: Stephen Tomasino 9-4-01

Test Coordinator/Date: Rebecca Schultz 9/4/01

Study Protocol: OPP Microprotocol #2001-30
OPP Microbiology Laboratory

Title: Performance Evaluation of T.B. Phene Disinfectant (EPA Reg. No. 211-36) against *Pseudomonas aeruginosa.*

Purpose: The purpose of this assay is to determine the effectiveness of an antimicrobial product against *P. aeruginosa* on a hard surface prepared approximately 28 days prior to use. This procedure simulates the test conditions previously used to determine the product's efficacy for registration purposes. The Antimicrobials Division (AD) of EPA's Office of Pesticide Programs (OPP) concurred on the test methodology and conditions associated with this study on 08/08/01 (see attached concurrence notice and the associated paperwork).

Test Identification: AOAC Use-dilution Test (Reference: Official Methods of Analysis. 1990. 15th Ed., Association of Official Analytical Chemists, Arlington, VA, Method 955.15). Test methodology is described in the following OPP Microbiology Laboratory SOP: MB-05-02 AOAC Use Dilution Method for Testing Disinfectants.

Test Substance: T.B. Phene Disinfectant
EPA Reg. No. 211-36

Sample No. 071201F257401-1, Lot No. 04041007
Sample No. 071201F257401-4, Lot No. 06281002
Sample No. 071201F257401-7, Lot No. 1228007

Active Ingredients:
Sodium ortho-benzyl-para-chlorophenate.....4.40%
Sodium ortho-phenylphenate.....2.82%
Sodium para-tertiary amylphenate.....2.49%
Inert Ingredients.....90.29%

(Chemical Analysis and Verification will be performed by the OPP Analytical Chemistry Branch, EPA Environmental Science Center, 701 Mapes Road, Ft. Meade, MD 20755-5350.)

Formulation: Liquid

Neutralizer: Letheen Broth

Controls: Performance and Sterility Assessment of Media and Reagents, and Carrier

Counts

Sponsor: EPA Office of Pesticide Programs, Antimicrobials Division and EPA Office of Enforcement and Compliance Assurance (OECA), Agriculture and Ecosystem Division, Agricultural Branch

Test Facility: OPP Microbiology Laboratory, EPA Environmental Science Center, 701 Mapes Road, Ft. Meade, MD 20755-5350.

Proposed Experimental Start Date: 09/06/01

Proposed Experimental Completion Date: 09/08/01

Test System: The test system used in this study is in accordance to the EPA data requirements for efficacy testing of hospital disinfectants used on hard surfaces. *P. aeruginosa* is the microbial agent administered in this study. The culture is obtained annually from the American Type Culture Collection (ATCC). Initial identification confirmation testing for quality control and the generation of the first series of stock cultures are performed concurrently. Selective media, Gram staining, and API strips or the Vitek 32 System for the automated identification of microorganisms are used for the initial and monthly identification confirmation. Generation of new stock cultures and confirmation testing are performed every 30 days. The microbial agent is assigned a Microbe Received and Microbe Expiration number (MRME). The MRME number consists of the date received (MR) and the date the reconstituted microbe expires (ME). The MRME culture notation will have a suffix; for *Pseudomonas* the suffix will be P. The notation for the test culture consists of the MRME number and notation for the monthly and daily transfer numbers. Also, TC is applied to indicate that it is a test culture. Test microbe culture maintenance and notation is described in the OPP Microbiology Laboratory SOP: MB-02-01 Test Microbes for the AOAC Use-Dilution Method, AOAC Germicidal Spray Product Test, Germicidal Towelette Product Test, and the AOAC Confirmatory Tuberculocidal Test Method: Culture Initiation, Culture Maintenance and Quality Control.

Experimental Design:

Test Microbes:	*Pseudomonas aeruginosa*, ATCC 15442
Subculture Media:	Letheen broth
Neutralizer:	Letheen broth
Carriers:	Carriers are polished stainless steel cylinders, 8 +/- 1 mm OD, 6 +/- mm ID, 10 +/- 1mm length; type 304 stainless

steel, SS 18-8 (S & L Metal Products Corp., Maspeth, NY Carriers are physically and biologically screened prior to use. A single test involves the evaluation of 60 inoculated carriers (one organism) against one product sample. In addition to the 60 carriers, 6 carriers are required to estimate carrier bacterial load and 6 more are included as extras. Thus, a total of 72 seeded carriers are required to perform a single test.

Method: AOAC Use-dilution Test (Reference: Official Methods of Analysis. 1990. 15th Ed., Association of Official Analytical Chemists, Arlington, VA, Method 955.15). Test methodology is described in the following OPP Microbiology Laboratory SOP: MB-05-02 AOAC Use Dilution Method for Testing Disinfectants.

Culture: The test culture is initiated by inoculating a 10 mL tube (20 mm x 100 mm) of nutrient broth or synthetic broth from a stock slant culture. The test culture is serially subcultured for at least three consecutive 24±2 hour periods in 10 mL of nutrient broth or synthetic broth at 37±1°C. The test culture is subcultured once again in nutrient broth or synthetic broth and incubated at 37±1°C for 48 to 54 hours. These cultures will be used to seed carriers. The appropriate amount of organic soil is added to the pooled culture prior to carrier inoculation.

Carrier Inoculation: Using a sterile hook, carriers are aseptically transferred into tubes of the test culture. After 15 minutes of contact time with the broth culture, the carriers are removed using a sterile wire hook. The carriers are drained by tapping them against the side of the tube. Each carrier is placed on its end in a sterile glass petri dish containing a double layer of sterile Whatman No. 2 filter paper. Carriers (12) are transferred from the culture tubes to each of 6 petri dishes. Once all (72) of the carriers have been transferred, they are dried for 40 minutes in a 37±1°C incubator. The seeded carriers are used the day of preparation.

Organic Soil Load: 5% Fetal Bovine Serum

Use Dilution: 1:128 (1 part disinfectant plus 127 parts sterile DI water) Product stored at room temperature under chain of custody

for approximately 28 days (see media preparation sheet for date and time of preparation).

Application: Contact time is 10 minutes.

Subculture: After the last carrier of a set (20 carriers) has been treated with the disinfectant, and the exposure time is complete, each carrier is transferred in order, into the primary subculture tubes containing 10 mL letheen broth. A minimum of 30 minutes after the last carrier is deposited, each carrier is transferred to a secondary subculture tube containing 10 mL of the letheen broth.

Incubation: The primary and secondary subculture tubes are incubated at 37°C for 48±2 hr. A positive result is one in which the broth culture appears turbid. A negative result is one in which the broth appears clear.

Confirmation: Gram stains are performed on smears taken from selected positive culture tubes. For the additional confirmatory tests, a loopful of broth from each selected culture tube is streaked on both TSA and selective media appropriate for the test organism and incubated for 24±2 hr at 37±1°C. The selective agar is checked for the correct reaction and the culture on the TSA plate is used for preparing the inoculum for the API strips or the Vitek 32 System for the automated identification of microorganisms.

Statistics: None Required.

Data Retention: Completed forms are archived in notebooks kept in locked file cabinets adjacent to offices D217. Archived data is subject to OPP's official retention schedule contained in the OPP Microbiology Laboratory SOP ADM-01: Preparation and Review of Disinfectant Performance Reports.

A final report will be prepared. One copy of the final report will be kept in the OPP lab's Quality Assurance files. The report with original signatures will be forwarded to AD. A copy is sent to OECA.

Protocol Approval:

Study Director/Date: Stephen Tomasino 9-4-01

Test Coordinator/Date: Rebecca S. [illegible] 9/4/01

EFFICACY TESTING
ANTIMICROBIAL PRODUCT TESTING PROGRAM
MASTER REFERENCE FOR TEST METHODS & CONDITIONS:
USE-DILUTION/GERMICIDAL SPRAY TEST

EPA REG. NO.	PRODUCT	TEST METHOD	TEST CONDITIONS	CONTACT TIME	NEUTRALIZER/ SUBCULTURE MEDIA	COMMENTS
211-36	T.B. PHENE (TRI-CEN)	AOAC Use-Dilution	Dilution: 1:128 (1 part disinfectant plus 127 parts diluent) This product can be used up to 28 days after preparation Organic soil: 5% fetal bovine serum Hard water: NO	10 min/20C	Letheen broth	Compare Product label To test Parameter Table; if Discrepancies, Contact OPP Microbiology Laboratory

Most recently stamped accepted label is dated May 10, 2001. Test parameters were extracted from MRID 446870-07 submitted by ViroMed. The submitted data were found satisfactory in the efficacy review dated 4-20-99. In total, three lots of product were tested against 60 carriers of each of three test organisms - *Staphylococcus aureus ATCC No. 6538, Salmonella choleraesuis*, ATCC No. 10708, and *Pseudomonas aeruginosa* ATCC No. 15442. Test parameters included: testing of a 1:128 dilution (prepared 28 days prior to testing) of product, incorporation of 5% fetal bovine serum into the inocula, and a contact time of 10 minutes at 20°C. The reports state that the carriers were dried for 40 minutes at 35 ± 2° C. Letheen broth is suitable for the neutralizer/subculture media.

The product label makes a tuberculocidal claim.

8/10/01

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TEST AOAC Use-Dilution

Michele Wingfield
08/08/2001 09:10 AM

To: Rebecca Schultheiss/DC/USEPA/US@EPA
cc:
Subject: Re: 211-36

Rebecca,

You have my concurrence on the testing parameters discussed for Tri-Cen (EPA Reg. No. 211-36).

Michele
Rebecca Schultheiss

Rebecca Schultheiss
08/01/01 01:01 PM

To: Michele Wingfield/DC/USEPA/US@EPA
cc: Stephen Tomasino/DC/USEPA/US@EPA, Cynthia Szymanski/DC/USEPA/US@EPA
Subject: 211-36

Michele, thank you for taking the time to assist our laboratory in sorting through testing issues for Tri-Cen (Reg 211-36). In accordance with our discussion this morning, we will test this product both at time zero and time 28 days for use-dilution and use letheen broth as the neutralizer for the CTB test. Could you please follow up with a concurrence to this memo for our testing file.

Data Summary Sheet

Subject	Details
Disinfectant Name	T.B. Phene
Registration No.	211-36
Sample No.	071201F257401-1
Lot No.	04041007
Expiration Date	NA
Registrant	Central Solutions, Inc.
City, State	Kansas City, Kansas
Test Date	09/05/01
Test Type	AOAC Use-Dilution Test
Organism	*Staphylococcus aureus*
Test Conditions:	
Soil Load	5% Fetal Bovine Serum
Water Type	Sterile Deionized Water
Water Hardness	NA
Use Dilution	1:128
Date Diluted	08/08/01
Waterbath Temp.	20°C
Contact Time	10 minutes
Drop Interval	30 seconds
Neutralizer	Letheen Broth
Subculture Media	Letheen Broth
Other	28 Day Post Preparation
Spray Distance (if applicable)	NA
Results:	
Carrier Counts	3.5×10^6
No. Carrier Sets with Growth	0
No. Carrier Sets without Growth	60
Total No. Carriers	60

Data Summary Sheet

Subject	Details
Disinfectant Name	T.B. Phene
Registration No.	211-36
Sample No.	071201F257401-4
Lot No.	06281002
Expiration Date	NA
Registrant	Central Solutions, Inc.
City, State	Kansas City, Kansas
Test Date	09/05/01
Test Type	AOAC Use-Dilution Test
Organism	*Staphylococcus aureus*
Test Conditions:	
Soil Load	5% Fetal Bovine Serum
Water Type	Sterile Deionized Water
Water Hardness	NA
Use Dilution	1:128
Date Diluted	08/08/01
Waterbath Temp.	20°C
Contact Time	10 minutes
Drop Interval	30 seconds
Neutralizer	Letheen Broth
Subculture Media	Letheen Broth
Other	28 Day Post Preparation
Spray Distance (if applicable)	NA
Results:	
Carrier Counts	3.5×10^6
No. Carrier Sets with Growth	0
No. Carrier Sets without Growth	60
Total No. Carriers	60

Data Summary Sheet

Subject	Details
Disinfectant Name	T.B. Phene
Registration No.	211-36
Sample No.	071201F257401-7
Lot No.	1228007
Expiration Date	NA
Registrant	Central Solutions, Inc.
City, State	Kansas City, Kansas
Test Date	09/05/01
Test Type	AOAC Use-Dilution Test
Organism	*Staphylococcus aureus*
Test Conditions:	
Soil Load	5% Fetal Bovine Serum
Water Type	Sterile Deionized Water
Water Hardness	NA
Use Dilution	1:128
Date Diluted	08/08/01
Waterbath Temp.	20°C
Contact Time	10 minutes
Drop Interval	30 seconds
Neutralizer	Letheen Broth
Subculture Media	Letheen Broth
Other	28 Day Post Preparation
Spray Distance (if applicable)	NA
Results:	
Carrier Counts	3.5×10^6
No. Carrier Sets with Growth	2
No. Carrier Sets without Growth	58
Total No. Carriers	60

Data Summary Sheet

Subject	Details
Disinfectant Name	T.B. Phene
Registration No.	211-36
Sample No.	071201F257401-1
Lot No.	04041007
Expiration Date	NA
Registrant	Central Solutions, Inc.
City, State	Kansas City, Kansas
Test Date	09/06/01
Test Type	AOAC Use-Dilution Test
Organism	*Pseudomonas aeruginosa*
Test Conditions:	
Soil Load	5% Fetal Bovine Serum
Water Type	Sterile Deionized Water
Water Hardness	NA
Use Dilution	1:128
Date Diluted	08/09/01
Waterbath Temp.	20°C
Contact Time	10 minutes
Drop Interval	30 seconds
Neutralizer	Letheen Broth
Subculture Media	Letheen Broth
Other	28 Day Post Preparation
Spray Distance (if applicable)	NA
Results:	
Carrier Counts	3.3×10^6
No. Carrier Sets with Growth	2
No. Carrier Sets without Growth	58
Total No. Carriers	60

Data Summary Sheet

Subject	Details
Disinfectant Name	T.B. Phene
Registration No.	211-36
Sample No.	071201F257401-4
Lot No.	06281002
Expiration Date	NA
Registrant	Central Solutions, Inc.
City, State	Kansas City, Kansas
Test Date	09/06/01
Test Type	AOAC Use-Dilution Test
Organism	*Pseudomonas aeruginosa*
Test Conditions:	
Soil Load	5% Fetal Bovine Serum
Water Type	Sterile Deionized Water
Water Hardness	NA
Use Dilution	1:128
Date Diluted	08/09/01
Waterbath Temp.	20°C
Contact Time	10 minutes
Drop Interval	30 seconds
Neutralizer	Letheen Broth
Subculture Media	Letheen Broth
Other	28 Day Post Preparation
Spray Distance (if applicable)	NA
Results:	
Carrier Counts	3.3×10^6
No. Carrier Sets with Growth	3
No. Carrier Sets without Growth	57
Total No. Carriers	60

Data Summary Sheet

Subject	Details
Disinfectant Name	T.B. Phene
Registration No.	211-36
Sample No.	071201F257401-7
Lot No.	1228007
Expiration Date	NA
Registrant	Central Solutions, Inc.
City, State	Kansas City, Kansas
Test Date	09/06/01
Test Type	AOAC Use-Dilution Test
Organism	*Pseudomonas aeruginosa*
Test Conditions:	
Soil Load	5% Fetal Bovine Serum
Water Type	Sterile Deionized Water
Water Hardness	NA
Use Dilution	1:128
Date Diluted	08/09/01
Waterbath Temp.	20°C
Contact Time	10 minutes
Drop Interval	30 seconds
Neutralizer	Letheen Broth
Subculture Media	Letheen Broth
Other	28 Day Post Preparation
Spray Distance (if applicable)	NA
Results:	
Carrier Counts	3.3×10^6
No. Carrier Sets with Growth	1
No. Carrier Sets without Growth	59
Total No. Carriers	60

Test Coordinator and Analyst Signature Page
OPP Microbiology Laboratory

TITLE OF DISINFECTANT PERFORMANCE REPORT:

Performance Report for the AOAC Use-Dilution Test of T.B. Phene 28 Day Post-Preparation (EPA Reg. 211-36)

Test Coordinator: Rebecca Schultz Date: 9.20.01

Analysts: [illegible] Date: 9.20.01
Marcus Rindal Date: 9.20.01
Kiran Verma Date: 9.20.01
Michele Cottrill Date: 9.20.01

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TEST AOAC Use Dilution

Signature Form for Personnel
OPP Microbiology Laboratory
September 2001

Analyst Name (print or type)	Signature	Initials
Michele Cottrill	Michele Cottrill	MC
Sharlita Harris	Sharlita Harris	SH
Susan Lawrence	Susan Lawrence	SL
Marcus (Marc) Rindal	Marcus Rindal	MR
Luisa C. Samalot-Gaud	[illegible]	[illegible]
Rebecca Schultheiss	Rebecca Schultheiss	RS
Stephen Tomasino	Stephen Tomasino	ST
Kiran Verma	Kiran Verma	KV
Mick Yanchulis	Mick Yanchulis	MY

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TEST AOAC Use-Dilution

AOAC Use-Dilution Test Information Sheet

OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	SOP	MB-05-02
Name	T.B. Phene ☆	Test Date	09-05-01
Sample No.	071201F257401-1	Comments:	
Lot No.	04041007	NA=not applicable	
Expiration Date	NA	☆ Tested 28 days post preparation	

TEST PARAMETERS/Confirmed by: RS			
H_2O Hardness ($CaCO_3$) ppm	Specified	Titrated (Buret)/Date/Init.	HACH/Date/Init.
	NA	NA / NA / NA	NA / NA / NA
Use Dilution	Specified	As Prepared/Date/Init.	
	1:128	T.B. Phene - 7mL DI Water - 889 mL / 08-08-01 / RV	
Organic Soil	Specified	As Prepared/Date/Init.	
	5% fetal bovine serum	15 mL Serum + 285 inoculum 9/5/01 / RS	
Neutralizer	Specified		
	Letheen Broth		
Temperature (°C)	Specified	Chiller Unit Display	Test Tube Waterbath
	20	Before: 20.0 After: 20.0	Before: 20 After: 20
Contact Time (minutes)	Specified	As Tested	
	10	10	
Other Parameters	Specified		
	According to label claim, this product can be used 28 days after preparation for *S. aureus* and *P. aeruginosa*		

TEST MICROBE INFORMATION/Confirmed by: RS				
Test Microbe	*Staphylococcus aureus*	48-54 Hour Culture		
Org. Control No.	MR050500ME121801-S-09-OAC	Date/Time	Initiated	Harvested
Avg. CFU/Carrier	3.5 x 10^6		9/3/01: 8:00 AM	9/5/01: 9:15 AM

REAGENT/MEDIA INFORMATION/Confirmed by: RS			
Reagent/Media	Prep. No.	Reagent/Media	Prep. No.
~~Letheen Broth~~	~~P-080201-01~~ EE RS 10-5-01	T.B. Phene	P-080801-04
Official Steel Carriers	P-081001-05	Letheen Broth	P-082001-01
Fetal Bovine Serum	P-090301-01		

AOAC Use-Dilution Test Information Sheet
OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	SOP	MB-05-02
Name	T.B. Phene ☆	Test Date	09-05-01
Sample No.	071201F257401-4	Comments:	
Lot No.	06281002	NA=not applicable	
Expiration Date	NA	☆ Tested 28 day post preparation	

TEST PARAMETERS/Confirmed by: RS			
H_2O Hardness ($CaCO_3$) ppm	Specified	Titrated (Buret)/Date/Init.	HACH/Date/Init.
	NA	NA / NA / NA	NA / NA / NA
Use Dilution	Specified	As Prepared/Date/Init.	
	1:128	T.B. Phene - 7mL / DI Water - 889mL / 08-08-01 / RW.	
Organic Soil	Specified	As Prepared/Date/Init.	
	5% fetal bovine serum	15 mL Serum + 285 inoculum / 9/5/01 / RS	
Neutralizer	Specified		
	Letheen Broth		
Temperature (°C)	Specified	Chiller Unit Display	Test Tube Waterbath
	20	Before: 20.0 After: 20.0	Before: 20 After: 20
Contact Time (minutes)	Specified	As Tested	
	10	10	
Other Parameters	Specified		
	According to label claim, this product can be used 28 days after preparation for *S. aureus* and *P. aeruginosa*		

TEST MICROBE INFORMATION/Confirmed by: RS				
Test Microbe	*Staphylococcus aureus*	48-54 Hour Culture		
Org. Control No.	MR050500ME121801-S-09-0ATC	Date/Time	Initiated	Harvested
Avg. CFU/Carrier	3.5×10^6		9/3/01: 8:00 AM	9/5/01: 9:15 AM

REAGENT/MEDIA INFORMATION/Confirmed by: RS			
Reagent/Media	Prep. No.	Reagent/Media	Prep. No.
~~Letheen Broth~~	~~P-080201-01~~ EE RS 10.5.01	T.B. Phene	P-080801-05 EE RS 10.5.01
Official Steel Carriers	P-081001-05	Letheen Broth	P-082008-01
Fetal Bovine Serum	P-090301-01		

AOAC Use-Dilution Test Information Sheet
OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	SOP	MB-05-02
Name	T.B. Phene ☆	Test Date	09-05-01
Sample No.	071201F257401-7	Comments:	
Lot No.	1228007	NA=not applicable	
Expiration Date	NA	☆ Tested 28 days post preparation	

TEST PARAMETERS/Confirmed by: RS			
H_2O Hardness ($CaCO_3$) ppm	Specified	Titrated (Buret)/Date/Init.	HACH/Date/Init.
	NA	NA / NA / NA	NA / NA / NA
Use Dilution	Specified	As Prepared/Date/Init.	
	1:128	T.B.Phene – 7mL / DI Water – 889mL / 08-08-01 / Kw	
Organic Soil	Specified	As Prepared/Date/Init.	
	5% fetal bovine serum	15mL serum / 9/5/01 / RS +285mL inoculum	
Neutralizer	Specified		
	Letheen Broth		
Temperature (°C)	Specified	Chiller Unit Display	Test Tube Waterbath
	20	Before: 20.0 After: 20.0	Before: 20 After: 20
Contact Time (minutes)	Specified	As Tested	
	10	10	
Other Parameters	Specified		
	According to label claim, this product can be used 28 days after preparation for *S. aureus* and *P. aeruginosa*		

TEST MICROBE INFORMATION/Confirmed by: RS				
Test Microbe	*Staphylococcus aureus*	48-54 Hour Culture		
Org. Control No.	MR050500ME121801-S-09-04TC	Date/Time	Initiated	Harvested
Avg. CFU/Carrier	3.5×10^6		9/3/01: 8:00AM	9/5/01: 9:15AM

REAGENT/MEDIA INFORMATION/Confirmed by: RS			
Reagent/Media	Prep. No.	Reagent/Media	Prep. No.
~~Letheen Broth~~	~~P-080201-01~~ EE	T.B. Phene	P-080801-06
Official Steel Carriers	P-081001-05 RS 9.5.01	Letheen Broth	P-082001-01
Fetal Bovine Serum	P-090301-01		

AOAC Use-Dilution Test Results Sheet

OPP Microbiology Laboratory

PRODUCT INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	Test Date	09-05-01
Name	T.B. Phene (28 day label claim)	Test Organism	*Staphylococcus aureus*
Sample No.	071201F257401-1		

CARRIER INFORMATION (to be completed by Analyst)		
Carrier Drop Time Interval	Carrier Set	Analyst
30 secs.	1-20	[illegible]
30 secs	21-40	[illegible]
30 secs.	41-60	[illegible]

TEST RESULTS									
Date Recorded/Initials	9/7/01 RS 1:30 pm *								
Primary Subculture / Secondary Subculture (carrier)									
1	2	3	4	5	6	7	8	9	10
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
11	12	13	14	15	16	17	18	19	20
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
21	22	23	24	25	26	27	28	29	30
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
31	32	33	34	35	36	37	38	39	40
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
41	42	43	44	45	46	47	48	49	50
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
51	52	53	54	55	56	57	58	59	60
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Results Summary			Number of Carrier Sets with Growth					0	
			Number of Carrier Sets without Growth					60	

Modifications/Comments: * Culture was removed from incubator at 1:30 pm RS 9/17/01

AOAC Use-Dilution Test Results Sheet

OPP Microbiology Laboratory

PRODUCT INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	Test Date	09-05-01
Name	T.B. Phene (28 day label claim)	Test Organism	*Staphylococcus aureus*
Sample No.	071201F257401-4		

CARRIER INFORMATION (to be completed by Analyst)		
Carrier Drop Time Interval	Carrier Set	Analyst
30 sec	1-20	RS
30 sec	21-40	RS
30 sec	41-60	RS

TEST RESULTS									
Date Recorded/Initials	9/7/01 RS 1:30* pm								
Primary Subculture / Secondary Subculture (carrier)									
1	2	3	4	5	6	7	8	9	10
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
11	12	13	14	15	16	17	18	19	20
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
21	22	23	24	25	26	27	28	29	30
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
31	32	33	34	35	36	37	38	39	40
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
41	42	43	44	45	46	47	48	49	50
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
51	52	53	54	55	56	57	58	59	60
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Results Summary	Number of Carrier Sets with Growth							0	
	Number of Carrier Sets without Growth							60	

Modifications/Comments: * Culture was removed from incubator at 1:30 pm RS 9/17/01

AOAC Use-Dilution Test Results Sheet
OPP Microbiology Laboratory

PRODUCT INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	Test Date	09-05-01
Name	T.B. Phene (28 day label claim)	Test Organism	*Staphylococcus aureus*
Sample No.	071201F257401-7		

CARRIER INFORMATION (to be completed by Analyst)		
Carrier Drop Time Interval	Carrier Set	Analyst
30 seconds	1-20	[illegible]
30 seconds	21-40	[illegible]
30 seconds	41-60	[illegible]

TEST RESULTS

Date Recorded/Initials	9/7/01 RS 1:30 pm ☆								
Primary Subculture / Secondary Subculture (carrier)									
1	2	3	4	5	6	7	8	9	10
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
11	12	13	14	15	16	17	18	19	20
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/+	0/0
21	22	23	24	25	26	27	28	29	30
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/+	0/0	0/0
31	32	33	34	35	36	37	38	39	40
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
41	42	43	44	45	46	47	48	49	50
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
51	52	53	54	55	56	57	58	59	60
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Results Summary			Number of Carrier Sets with Growth					2 ☆☆	
			Number of Carrier Sets without Growth					58	

Modifications/Comments: ☆ Culture was removed from incubator at 1:30 pm RS 9/17/01 ☆☆ Confirmed to be the test organism RS 9/19/01 See confirmation sheet RS 9/20/01

AOAC Use-Dilution Test: Time Recording Sheet for Carrier Inoculation Steps

OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS	
Test Date	09-05-01
Type of Test	AOAC Use-Dilution Test (UDT) RS 9/17/01
Product Reg. No.	211-36
Product Name	T.B. Phene (28 day label claim)
Sample No(s).	071201F257401-1 and 071201F257401-4 and 071201F257401-7
Organism	*Staphylococcus aureus*

Initials/Date	Test ID	Inoculum Settle Time*		Carrier Seeding Time*		Carrier Dry Time*	
		Start Time	End Time	Start Time	End Time	Start Time	End Time
RS 9.5.01	UDT	9:24 AM 00:00	9:34 AM 10:00	9:51 AM 00:00	10:06 AM 15:00	10:25 AM 00:00	11:05 AM 40:00
		/	/	/	/	/	/
		/	/	/	/	/	/
		/	/	/	/	/	/
		/	/	/	/	/	/
		/	/	/	/	/	/

* Recorded from laboratory clock/and timer.

MB-05Form1.wpd

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TEST AOAC Use-Dilution

AOAC Use-Dilution Test: Time Recording Sheet for Carrier Transfers

OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: DS	
Test Date	09-05-01
Type of Test	AOAC Use-Dilution Test
Product Reg. No.	211-36
Product Name	T.B. Phene (28 day label claim)
Sample No(s).	071201F257401-1
Organism	*Staphylococcus aureus*

Initials/date	Set	Drop Interval	Carrier Drop Start Time (into the disinfectant)		Carrier Drop End Time (into the primary subculture/neutralizer media)		Carrier Transfer (into secondary subculture)
			Clock	Timer	Clock	Timer	Start Time[1]
[illegible] 09-05-01	1-20	30 sec.	11:32 AM	00:30	11:52 AM	20:00	12:42 pm [illegible]
[illegible] 09-05-01	21-40	30 sec.	11:55 AM	00:30	12:15 pm	20:00	12:54 pm [illegible]
[illegible] 09-05-01	41-60	30 sec.	12:19 pm	00:30	12:39 pm	20:00	1:11 pm [illegible]

Comments:

1 Carrier transfer into secondary subculture (time elapsed after last carrier dropped in primary); taken from clock

MB05Form2.wpd

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TEST AOAC Use-Dilution

AOAC Use-Dilution Test: Time Recording Sheet for Carrier Transfers

OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS	
Test Date	09-05-01
Type of Test	AOAC Use-Dilution Test
Product Reg. No.	211-36
Product Name	T.B. Phene (28 day label claim)
Sample No(s).	071201F257401-4
Organism	*Staphylococcus aureus*

Initials/date	Set	Drop Interval	Carrier Drop Start Time (into the disinfectant)		Carrier Drop End Time (into the primary subculture/neutralizer media)		Carrier Transfer (into secondary subculture)
			Clock	Timer	Clock	Timer	Start Time[1]
RS 09-05-01	1-20	30 sec.	11:25 AM	00:30	11:45 AM	20:00	12:36 pm RS
RS 09-05-01	21-40	30 sec.	11:50 AM	00:30	12:10 pm	20:00	12:46 pm RS
RS 09-05-01	41-60	30 sec.	12:15 AM	00:30	12:35 pm	20:00	1:06 pm RS

Comments:

1 Carrier transfer into secondary subculture (time elapsed after last carrier dropped in primary); taken from clock

MB05Form2.wpd

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TEST AOAC Use-Dilution

AOAC Use-Dilution Test: Time Recording Sheet for Carrier Transfers

OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RB	
Test Date	09-05-01
Type of Test	AOAC Use-Dilution Test
Product Reg. No.	211-36
Product Name	T.B. Phene (28 day label claim)
Sample No(s).	071201F257401-7
Organism	*Staphylococcus aureus*

Initials/date	Set	Drop Interval	Carrier Drop Start Time (into the disinfectant)		Carrier Drop End Time (into the primary subculture/neutralizer media)		Carrier Transfer (into secondary subculture)
			Clock	Timer	Clock	Timer	Start Time[1]
MK 09-05-01	1-20	30 sec.	11:25am	00:30	11:45am	20:00	12:32pm MK
MK 09-05-01	21-40	30 sec.	11:48am	00:30	12:08pm	20:00	12:42pm MK
MK 09-05-01	41-60	30 sec.	12:10pm	00:30	12:30pm	20:00	1:00pm MK

Comments:

1 Carrier transfer into secondary subculture (time elapsed after last carrier dropped in primary); taken from clock

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REG NO. 211-36

TEST AOAC Use-Dilution

Serial Dilution/Plating Tracking Form
OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS				
EPA Reg. No.	Name	T.B. Phene (28 day label claim)		
211-36	Sample No. (s)	071201F257401-1 and 071201F257401-4 and 071201F257401-7		
EPA Reg. No.	Name	NA		
NA	Sample No. (s)	NA		
Test Date		~~09-06-01~~ 9-5-01 EE RS 9/17/01	SOP	MB-04-01
Organism		~~*Pseudomonas aeruginosa*~~ *Staphylococcus aureus* EE RS 9/17/01		

Confirmed by: RS	Dilution Tube							
	1	2	3	4	5	6	7	8
Vol. In Dil. Tube prior to Addition	9 mL	9 mL	9 mL	9 mL	9 mL			
Volume Added to Dil. Tube	1 mL	1 mL	1 mL	1 mL	1 mL			
Overall Dilution in Dil. Tube	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-5}			
Volume Plated			1 mL	1 mL	1 mL			
Overall Dilution on Plate			10^{-3}	10^{-4}	10^{-5}			
Number of Plates per Dilution			2	2	2			
Media Plated Onto	TSA							
Number of Carriers Analyzed	6 carriers selected at random							

Comments: M. Cottrill Sonicated 6 carriers for one minute at 11:30am.
Dilutions and plating completed by 12:45pm. MC 9/5/01

REAGENT/MEDIA INFORMATION/Confirmed by: RS			
Reagent/Media	Prep. No.	Reagent/Media	Prep. No.
TSA	P-082901-02		
PBDW	P-072301-01		
Letheen Broth	~~P-080201-01~~	P-082001-01	

EE RS 10.5.01

MB-04Form1.wpd

Carrier Count Data Sheet for the AOAC Use-Dilution ~~Test Method~~

OPP Microbiology Laboratory

TEST INFORMATION /Confirmed by: RS			
EPA Reg. No.	211-36	Test Date	09-05-01
Name	T.B. Phene (28 day label claim)	Organism	*Staphylococcus aureus*
Sample No.	071201F257401-1 and -4 and -7	Sample No.	

RESULTS						
Date/Initials	9/6/01 RS 1:42pm					
Plating method	Pour Plate Method					
Carrier No. / Dilution	CFU per Dilution Plate (2)				Average CFU per mL per Carrier	Average CFU per Carrier†
	10^{-3}	10^{-4}	10^{-5}			
1	324 | 197	38 | 16	2 | 1	|	2.9×10^5	2.9×10^6
2	344 | TNTC	35 | 33	2 | 3	|	3.4×10^5	3.4×10^6
3	TNTC | TNTC	38 | 41	2 | 2	|	4.0×10^5	4.0×10^6
4	TNTC | TNTC	33 | 31	2 | 2	|	3.2×10^5	3.2×10^6
5	TNTC | TNTC	41 | 37	2 | 2	|	3.9×10^5	3.9×10^6
6	TNTC | TNTC	39 | 32	3 | 3	|	3.6×10^5	3.6×10^6
Avg. CFU per Carrier for all Carriers Tested:						3.5×10^6

† Values reflect dilution factor for volume of media in initial tube receiving carrier.

Test Microbe Confirmation Sheet
OPP Microbiology Laboratory

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REG. NO. 211-36
TEST HOAC use-dilution

TEST INFORMATION/Confirmed by: NS			
EPA Reg. No.	211-36	Test Date	09-05-01
Name	T.B. Phene (28 day label claim)	Test Organism	*Staphylococcus aureus*
Sample No.	071201F257401-7	Comments:	

Source: Tube/Plate ID	Date/ Initials	Stain Results*	Media Information			Results		
			Type	Prep. No.	Inc. Time/ Temp.	Date/ Initials	Colony Characteristics (1)	API Test**/Vitek ID (if applicable)
19/2	9.7.01 NS	GPC		NA NS 9/17/01				
28/2	9.7.01 NS	GPC						
19/2	9.10.01 NS	NA	Mannitol Salt Agar	P-07~~12~~01-02 16 EEO NS 10.5.01	24hrs 37°C	9.11.01 NS	circular, small, yellow colonies, agar fluorescent yellow	NA
19/2	9.10.01 NS	NA	TSA	P-082901-02	24hrs 37°C	9.11.01 NS	small, circular, yellow glistening colonies	#60-0 identified as S. aureus
28/2	9.10.01 NS	NA	Mannitol Salt Agar	P-07~~12~~01-02 16 EEO NS 10.5.01	24hrs 37°C	9.11.01 NS	circular, small, yellow colonies, agar fluorescent yellow	NA
28/2	9.10.01 NS	NA	TSA	P-082901-02	24hrs 37°C	9.11.01 NS	small, circular, yellow glistening colonies	#61-0 identified as S. aureus
			NA NS 9/17/01					

* Record Acid Fast or Gram Stain results as GPC=gram positive cocci, GNR=gram negative rods, AFR=acid fast rods, GPR=Gram positive rods.
** API numerical profile number

EEO NS 9/26/01

(1) See Table ~~10.3~~ 1 Section 10.3 for typical Growth Characteristics
NS 9/20/01

EEO NS 10.5.01 Table 1 Section 10.3 can be found in SOP MB-02-01 pg 10

AOAC Use-Dilution Test Information Sheet
OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	SOP	MB-05-02
Name	T.B. Phene ☆	Test Date	09-06-01
Sample No.	071201F257401-1	Comments:	
Lot No.	04041007	NA=not applicable	
Expiration Date	NA	☆ Tested 28 days post preparation	

TEST PARAMETERS/Confirmed by: RS			
H_2O Hardness ($CaCO_3$) ppm	Specified	Titrated (Buret)/Date/Init.	HACH/Date/Init.
	NA	NA / NA / NA	NA / NA / NA
Use Dilution	Specified	As Prepared/Date/Init.	
	1:128	T.B. Phene=7 ml / DI Water=889 ml 08-09-01 / RW.	
Organic Soil	Specified	As Prepared/Date/Init.	
	5% fetal bovine serum	15 mL serum + / 285 mL inoculum 9.6.01 / MR	
Neutralizer	Specified		
	Letheen Broth		
Temperature (°C)	Specified	Chiller Unit Display	Test Tube Waterbath
	20	Before: 20.0 After: 20.0	Before: 20 After: 20
Contact Time (minutes)	Specified	As Tested	
	10	10	
Other Parameters	Specified		
	According to label claim, this product can be used 28 days after preparation for *S. aureus* and *P. aeruginosa*		

TEST MICROBE INFORMATION/Confirmed by: RS				
Test Microbe	*Pseudomonas aeruginosa*	48-54 Hour Culture		
Org. Control No.	MR050300ME121801-P-09-05TC	Date/Time	Initiated	Harvested
Avg. CFU/Carrier	3.3×10^6		9/4/01: 8:15 am	9/6/01: 8:15 am

REAGENT/MEDIA INFORMATION/Confirmed by: RS			
Reagent/Media	Prep. No.	Reagent/Media	Prep. No.
~~Letheen Broth~~	~~P-080201-02~~ LB RS 10-5-01	T.B. Phene	P-080901-02
Official Steel Carriers	P-081001-05	Letheen Broth	P-082101-02
Fetal Bovine Serum	P-090401-02		

AOAC Use-Dilution Test Information Sheet
OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	SOP	MB-05-02
Name	T.B. Phene ☆	Test Date	09-06-01
Sample No.	071201F257401-7	Comments:	
Lot No.	1228007	NA=not applicable	
Expiration Date	NA	☆ Tested 28 days post-preparation	

TEST PARAMETERS/Confirmed by: RS			
H_2O Hardness ($CaCO_3$) ppm	Specified	Titrated (Buret)/Date/Init.	HACH/Date/Init.
	NA	NA / NA / NA	NA / NA / NA
Use Dilution	Specified	As Prepared/Date/Init.	
	1:128	T.B Phene - 7mL DI Water - 889 mL / 08-09-01 / KV	
Organic Soil	Specified	As Prepared/Date/Init.	
	5% fetal bovine serum	15mL serum + 285mL inoculum / 9.6.01 / MC	
Neutralizer	Specified		
	Letheen Broth		
Temperature (°C)	Specified	Chiller Unit Display	Test Tube Waterbath
	20	Before: 20.0 After: 20.0	Before: 20 After: 20
Contact Time (minutes)	Specified	As Tested	
	10	10	
Other Parameters	Specified		
	According to label claim, this product can be used 28 days after preparation for *S. aureus* and *P. aeruginosa*		

TEST MICROBE INFORMATION/Confirmed by: RS				
Test Microbe	*Pseudomonas aeruginosa*	48-54 Hour Culture		
Org. Control No.	MR050300ME121801-P-09-05TC	Date/Time	Initiated	Harvested
Avg. CFU/Carrier	3.3×10^6		9/4/01: 8:15 AM	9/6/01: 8:15 AM

REAGENT/MEDIA INFORMATION/Confirmed by: RS			
Reagent/Media	Prep. No.	Reagent/Media	Prep. No.
~~Letheen Broth~~	~~P-080201-02~~ EE RS 10-5-01	T.B. Phene	P-080901-04
Official Steel Carriers	P-081001-05	Letheen Broth	P-082101-02
Fetal Bovine Serum	P-090401-02		

AOAC Use-Dilution Test Information Sheet
OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	SOP	MB-05-02
Name	T.B. Phene ☆	Test Date	09-06-01
Sample No.	071201F257401-4	Comments:	
Lot No.	06281002	NA=not applicable	
Expiration Date	NA	☆ Tested 28 days post preparation	

TEST PARAMETERS/Confirmed by: RS			
H_2O Hardness ($CaCO_3$) ppm	Specified	Titrated (Buret)/Date/Init.	HACH/Date/Init.
	NA	NA / NA / NA	NA / NA / NA
Use Dilution	Specified	As Prepared/Date/Init.	
	1:128	T.B. Phene - 7mL / DI Water - 889mL / 08-09-01 / RW	
Organic Soil	Specified	As Prepared/Date/Init.	
	5% fetal bovine serum	15mL serum + / 285mL inoculum / 9.6.01 / (RW)	
Neutralizer	Specified		
	Letheen Broth		
Temperature (°C)	Specified	Chiller Unit Display	Test Tube Waterbath
	20	Before: 20.0 After: 20.0	Before: 20 After: 20
Contact Time (minutes)	Specified	As Tested	
	10	10	
Other Parameters	Specified		
	According to label claim, this product can be used 28 days after preparation for *S. aureus* and *P. aeruginosa*		

TEST MICROBE INFORMATION/Confirmed by: RS				
Test Microbe	*Pseudomonas aeruginosa*	48-54 Hour Culture		
Org. Control No.	MR050300ME121801-P-09-05TC	Date/Time	Initiated	Harvested
Avg. CFU/Carrier	3.3×10^6		9/4/01: 8:15 AM	9/6/01: 8:15 AM

REAGENT/MEDIA INFORMATION/Confirmed by: RS			
Reagent/Media	Prep. No.	Reagent/Media	Prep. No.
~~Letheen Broth~~	~~P-080201-02~~ EF RS 10-5-01	T.B. Phene	P-080901-03
Official Steel Carriers	P-081001-05	Letheen Broth	P-082101-02
Fetal Bovine Serum	P-090401-02		

AOAC Use-Dilution Test Results Sheet
OPP Microbiology Laboratory

PRODUCT INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	Test Date	09-06-01
Name	T.B. Phene (28 day preparation)	Test Organism	*Pseudomonas aeruginosa*
Sample No.	071201F257401-1		

CARRIER INFORMATION (to be completed by Analyst)		
Carrier Drop Time Interval	Carrier Set	Analyst
30 secs.	1-20	[illegible]
30 secs.	21-40	[illegible]
30 secs.	41-60	[illegible]

TEST RESULTS

Date Recorded/Initials	9-8-01 / MC 12:15pm								
Primary Subculture / Secondary Subculture (carrier)									
1	2	3	4	5	6	7	8	9	10
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
11	12	13	14	15	16	17	18	19	20
0/0	0/+	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
21	22	23	24	25	26	27	28	29	30
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
31	32	33	34	35	36	37	38	39	40
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
41	42	43	44	45	46	47	48	49	50
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
51	52	53	54	55	56	57	58	59	60
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
Results Summary			Number of Carrier Sets with Growth					1 ☆	
			Number of Carrier Sets without Growth					59	

Modifications/Comments: ☆ Confirmed to be the test organism RS 9/19/01 See Confirmation Sheet RS 9/20/01

AOAC Use-Dilution Test Results Sheet
OPP Microbiology Laboratory

PRODUCT INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	Test Date	09-06-01
Name	T.B. Phene (28 day label claim)	Test Organism	*Pseudomonas aeruginosa*
Sample No.	071201F257401-4		

CARRIER INFORMATION (to be completed by Analyst)		
Carrier Drop Time Interval	Carrier Set	Analyst
30 sec	1-20	RS
30 sec	21-40	RS
30 sec	41-60	RS

TEST RESULTS

Date Recorded/Initials: 9-8-01 / MC 12:30 pm

Primary Subculture / Secondary Subculture (carrier)

1	2	3	4	5	6	7	8	9	10
0/0	0/0	0/0	0/0	0/+	0/+	0/0	0/0	0/0	0/0
11	12	13	14	15	16 EE. MC 9-8-01	17	18	19	20
0/0	0/0	0/0	0/0	0/0	0/Ø+	0/0	0/0	0/0	0/0
21	22	23	24	25	26	27	28	29	30
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
31	32	33	34	35	36	37	38	39	40
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
41	42	43	44	45	46	47	48	49	50
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
51	52	53	54	55	56	57	58	59	60
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0

Results Summary		
	Number of Carrier Sets with Growth	3*
	Number of Carrier Sets without Growth	57

Modifications/Comments: * Confirmed to be the test organism RS 9/17/01 See Confirmation Sheet RS 9/20/01

AOAC Use-Dilution Test Results Sheet
OPP Microbiology Laboratory

PRODUCT INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	Test Date	09-06-01
Name	T.B. Phene (28 day label claim)	Test Organism	*Pseudomonas aeruginosa*
Sample No.	071201F257401-7		

CARRIER INFORMATION (to be completed by Analyst)		
Carrier Drop Time Interval	Carrier Set	Analyst
30 seconds	1-20	MS
30 seconds	21-40	MS
30 seconds	41-60	MS

TEST RESULTS

Date Recorded/Initials: 9-8-01/mc 12:45pm

Primary Subculture / Secondary Subculture (carrier)

1	2	3	4	5	6	7	8	9	10
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
11	12	13	14	15	16	17	18	19	20
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/+	0/0
21	22	23	24	25	26	27	28	29	30
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
31	32	33	34	35	36	37	38	39	40
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0
41	42	43	44	45	46	47	48	49	50
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/+
51	52	53	54	55	56	57	58	59	60
0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0	0/0 **

Results Summary		
	Number of Carrier Sets with Growth	2 *
	Number of Carrier Sets without Growth	58

Modifications/Comments: Confirmed to be the test organism RS 9/17/01 See Confirmation Sheet RS 9/20/01

E.E.O. for carriers 51-60. MC 9-7-01

** Primary Subculture tubes and secondary subculture tubes for carriers 51 through 60 were read on 9-8-01 but not recorded. All tubes were negative. MC 9-19-01

AOAC Use-Dilution Test: Time Recording Sheet for Carrier Inoculation Steps

OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS	
Test Date	09-06-01
Type of Test	AOAC Use-Dilution Test (UDT) RS 9/17/01
Product Reg. No.	211-36
Product Name	T.B. Phene (28 day label claim)
Sample No(s).	071201F257401-1 and 071201F257401-4 and 071201F257401-7
Organism	*Pseudomonas aeruginosa*

Initials/Date	Test ID	Inoculum Settle Time*		Carrier Seeding Time*		Carrier Dry Time*	
		Start Time	End Time	Start Time	End Time	Start Time	End Time
9.6.01 (MP)	UDT	8:45am/00:00	8:55am/10:00	9:19am/00:00	9:34am/15:00	10:05am/00:00	10:45am/40:00
		/	/	/	/	/	/
		/	/	/	/	/	/
		/	/	/	/	/	/
		/	/	/	/	/	/
		/	/	/	/	/	/

* Recorded from laboratory clock/and timer.

MB-05Form1.wpd

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TEST AOAC Use-Dilution

AOAC Use-Dilution Test: Time Recording Sheet for Carrier Transfers

OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS	
Test Date	09-06-01
Type of Test	AOAC Use-Dilution Test
Product Reg. No.	211-36
Product Name	T.B. Phene (28 day label claim)
Sample No(s).	071201F257401-1
Organism	*Pseudomonas aeruginosa*

Initials/date	Set	Drop Interval	Carrier Drop Start Time (into the disinfectant)		Carrier Drop End Time (into the primary subculture/neutralizer media)		Carrier Transfer (into secondary subculture)
			Clock	Timer	Clock	Timer	Start Time[1]
09-06-01	1-20	30 sec.	10:59 Am	00:30	11:19 am	20:00	12:06 pm
09-06-01	21-40	30 sec.	11:21 Am	00:30	11:41 Am	20:00	12:27 pm RS
09-06-01	41-60	30 sec.	11:43 Am	00:30	12:03 pm	20:00	12:54 pm RS

Comments:

1 Carrier transfer into secondary subculture (time elapsed after last carrier dropped in primary); taken from clock

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TEST AOAC Use-Dilution

AOAC Use-Dilution Test: Time Recording Sheet for Carrier Transfers

OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS	
Test Date	09-06-01
Type of Test	AOAC Use-Dilution Test
Product Reg. No.	211-36
Product Name	T.B. Phene (28 day label claim)
Sample No(s).	071201F257401-4
Organism	*Pseudomonas aeruginosa*

Initials/date	Set	Drop Interval	Carrier Drop Start Time (into the disinfectant)		Carrier Drop End Time (into the primary subculture/neutralizer media)		Carrier Transfer (into secondary subculture)
			Clock	Timer	Clock	Timer	Start Time[1]
RS 09-06-01	1-20	30 sec.	10:56 AM	00:30	11:16 AM	20:00	12:00 pm RS
RS 09-06-01	21-40	30 sec.	11:17 AM	00:30	11:37 AM	20:00	12:16 pm RS
RS 09-06-01	41-60	30 sec.	11:39 AM	00:30	11:59 AM	20:00	12:38 pm RS

Comments:

1 Carrier transfer into secondary subculture (time elapsed after last carrier dropped in primary); taken from clock

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TEST AOAC Use-Dilution

AOAC Use-Dilution Test: Time Recording Sheet for Carrier Transfers

OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RB	
Test Date	09-06-01
Type of Test	AOAC Use-Dilution Test
Product Reg. No.	211-36
Product Name	T.B. Phene (28 day label claim)
Sample No(s).	071201F257401-7
Organism	*Pseudomonas aeruginosa*

Initials/date	Set	Drop Interval	Carrier Drop Start Time (into the disinfectant)		Carrier Drop End Time (into the primary subculture/neutralizer media)		Carrier Transfer (into secondary subculture)
			Clock	Timer	Clock	Timer	Start Time[1]
MC 09-06-01	1-20	30 sec.	10:58am	00:30	11:18am	20:00	12:05pm MC
MC 09-06-01	21-40	30 sec.	11:20am	00:30	11:40am	20:00	12:15pm MC
MC 09-06-01	41-60	30 sec.	11:42am	00:30	12:02pm	20:00	12:35pm MC

Comments:

1 Carrier transfer into secondary subculture (time elapsed after last carrier dropped in primary); taken from clock

MB05Form2.wpd

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TEST AOAC Use-Dilution

Serial Dilution/Plating Tracking Form
OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS				
EPA Reg. No. 211-36	Name	T.B. Phene (28 day label claim)		
	Sample No. (s)	071201F257401-1 and 071201F257401-4 and 071201F257401-7		
EPA Reg. No. NA	Name	NA		
	Sample No. (s)	NA		
Test Date		09-06-01	SOP	MB-04-01
Organism		*Pseudomonas aeruginosa*		

Confirmed by: RS	Dilution Tube							
	1	2	3	4	5	6	7	8
Vol. In Dil. Tube prior to Addition	9 mL	9 mL	9 mL	9 mL	9 mL			
Volume Added to Dil. Tube	1 mL	1 mL	1 mL	1 mL	1 mL			
Overall Dilution in Dil. Tube	10^{-1}	10^{-2}	10^{-3}	10^{-4}	10^{-5}			
Volume Plated			1 mL	1 mL	1 mL			
Overall Dilution on Plate			10^{-3}	10^{-4}	10^{-5}			
Number of Plates per Dilution			2	2	2			
Media Plated Onto	TSA							
Number of Carriers Analyzed	6 carriers selected at random							

Comments: RS sonicated carriers for 1 min @ 10:54AM
Dilutions and plating completed by [illegible] around
1:00pm · 9·6·01 [illegible]

REAGENT/MEDIA INFORMATION/Confirmed by: RS			
Reagent/Media	Prep. No.	Reagent/Media	Prep. No.
TSA	P-082901-02		
PBDW	P-072301-01		
Letheen Broth	~~P-080201-02~~	P-082101-02	

EE RS 10.5.01

Carrier Count Data Sheet for the AOAC Use-Dilution Test Method

OPP Microbiology Laboratory

TEST INFORMATION /Confirmed by: RS			
EPA Reg. No.	211-36	Test Date	09-06-01
Name	T.B. Phene (28 day label claim)	Organism	*Pseudomonas aeruginosa*
Sample No.	071201F257401-1 and -4 and -7	Sample No.	

RESULTS						
Date/Initials	9/7/01 RS					
Plating method	Pour Plate Method					
Carrier No. / Dilution	CFU per Dilution Plate (2)				Average CFU per mL per Carrier	Average CFU per Carrier†
	10^{-3}	10^{-4}	10^{-5}			
1	TNTC | 180	39 | 16	5 | 2	|	2.9×10^5	2.9×10^6
2	TNTC | TNTC	44 | 46	2 | 4	|	4.5×10^5	4.5×10^6
3	TNTC | 125	43 | 18	3 | 0	|	2.8×10^5	2.8×10^6
4	322 | 265	19 | 31	3 | 0	|	2.9×10^5	2.9×10^6
5	291 | 243	23 | 11	1 | 2	|	2.7×10^5	2.7×10^6
6	TNTC | TNTC	42 | 35	0 | 3	|	3.9×10^5	3.9×10^6
Avg. CFU per Carrier for all Carriers Tested:						3.3×10^6

† Values reflect dilution factor for volume of media in initial tube receiving carrier.

Test Microbe Confirmation Sheet
OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36 28 EE RS 9/20/01	Test Date	09-06-01
Name	T.B. Phene (~~29~~ 28 day label claim)	Test Organism	*Pseudomonas aeruginosa*
Sample No.	071201F257401-7	Comments:	

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REG. NO. 211-36
TEST Page Use Dilution

Source: Tube/Plate ID	Date/ Initials	Stain Results*	Media Information: Type	Prep. No.	Inc. Time/ Temp.	Results: Date/ Initials	Colony Characteristics (1)	API Test**/Vitek ID (if applicable)
19/2	9.10.01 RS	GNR	Pseudosel Agar	P-071601-01	24hrs 37°C	9.11.01 RS	Circular, small opaque/green colonies, Agar fluorescent green	NA
19/2	9.10.01 RS	NA	TSA	P-082901-02	24hr 37°C	9.11.01 RS	Opaque raised spreading colonies	#63-0 identified as P. aeruginosa
50/2	9.10.01 RS	GNR	Pseudosel Agar	P-071601-01	24hr 37°C	9.11.01 RS	Circular, small opaque/green colonies, Agar fluorescent green	NA
50/2	9.10.01 RS	NA	TSA	P-082901-02	24hr 37°C	9.11.01 RS	Opaque raised spreading colonies	#62-0 identified as P. aeruginosa
			NA	RS 9/17/01				

* Record Acid Fast or Gram Stain results as GPC=gram positive cocci, GNR=gram negative rods, AFR=acid fast rods, GPR=Gram positive rods.
** API numerical profile number

EEO RS 9/26/01

(1) See Table 1 Section 10.3 ~~10.3~~ for Typical Growth Characteristics
RS 9/20/01

EEO RS 10.5.01 Table 1 Section 10.3 can be found in SOP MB-02-01 pg 10

Test Microbe Confirmation Sheet
OPP Microbiology Laboratory

TEST INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	Test Date	09-06-01
Name	T.B. Phene (28 day label claim)	Test Organism	*Pseudomonas aeruginosa*
Sample No.	071201F257401-4	Comments:	

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REG NO. 211-36
TEST Hope Use Dilution

Source: Tube/Plate ID	Date/ Initials	Stain Results*	Media Information: Type	Prep. No.	Inc. Time/ Temp.	Results: Date/ Initials	Colony Characteristics (1)	API Test**/~~Vitek ID~~ (if applicable)
5/2	9.10.01 RS	GNR	Pseudosel Agar	P-071601-01	24hrs 37°C	9.11.01 RS	circular small opaque green colonies Agar	NA
5/2	9.10.01 RS	NA	TSA	P-082901-02	24hrs 37°C	9.11.01 RS	fluorescent green opaque raised spreading colonies	#66-0 identified as P.aeruginosa
6/2	9.10.01 RS	GNR	Pseudosel Agar	P-071601-01	24hrs 37°C	9.11.01 RS	circular small opaque green colonies Agar	NA
6/2	9.10.01 RS	NA	TSA	P.082901-02	24hrs 37°C	9.11.01 RS	fluorescent green opaque raised spreading colonies	#65-0 unidentified
16/2	9.10.01 RS	GNR	Pseudosel Agar	P-071601-01	24hrs 37°C	9.11.01 RS	circular small opaque green colonies Agar	NA
16/2	9.10.01 RS	NA	TSA	P-082901-02	24hrs 37°C	9.11.01 RS	fluorescent green opaque raised spreading colonies	#64-0 identified as P.aeruginosa
6/2	9.13.01 RS	NA	TSA	P-082901-02	24hrs 37°C	9.14.01 RS	opaque raised spreading colonies	#68-0 identified as P.aeruginosa
			← NA	RS 9/17/01	→			

* Record Acid Fast or Gram Stain results as GPC=gram positive cocci, GNR=gram negative rods, AFR=acid fast rods, GPR=Gram positive rods.
** API numerical profile number EEO RS 9/26/01

(1) See Table 1 ~~10.3~~ Section 10.3 for Typical Growth Characteristics
RS 9/20/01

EEO RS 10.5.01 Table 1 Section 10.3 can be found in SOP MB-02-01 pg 10

Test Microbe Confirmation Sheet
OPP Microbiology Laboratory

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REG. NO. 211-36
TEST Phase Use-Dilution

TEST INFORMATION/Confirmed by: RS			
EPA Reg. No.	211-36	Test Date	09-06-01
Name	T.B. Phene (28 day label claim)	Test Organism	*Pseudomonas aeruginosa*
Sample No.	071201F257401-1	Comments:	

Source: Tube/Plate ID	Date/ Initials	Stain Results*	Media Information			Results		
			Type	Prep. No.	Inc. Time/ Temp.	Date/ Initials	Colony Characteristics (1)	API Test** (Vitek ID) (if applicable)
12/2	9.10.01 RS	GNR	Pseudosel Agar	P-071601-01	24hrs 37°C	9/11/01 RS	Circular small opaque/green distinct. Agar	NA
12/2	9.10.01 RS	NA	TSA	P-082901-02	24hrs 37°C	9/11/01 RS	fluorescent green opaque raised spreading edges	#67-0 identified as P. aeruginosa

NA RS 9/17/01

* Record Acid Fast or Gram Stain results as GPC=gram positive cocci, GNR=gram negative rods, AFR=acid fast rods, GPR=Gram positive rods.
** API numerical profile number EEO RS 9/26/01

(1) See Table ~~10.7~~ 1 section 10.3 for Typical Growth Characteristics
RS 9/20/01

EEO RS 10.5.01 Table 1 Section 10.3 can be found in SOP MB-02-01 pg 10.

VITEK Microbe Identification Log
OPP/Microbiology Laboratory

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REG. NO. 211-36
TEST Home Use-Dilution

VITEK CONFIRMATION RECORD LOG SHEET

Date/Init.	Vitek No.#	Card*	Test Date	Product Reg. No.	Test Organism	Sample No.	Sour
[redacted]							
Comments: [redacted]							
[redacted]							
Comments: [redacted]							
[redacted]							
Comments: [redacted]							
9/11/01 RS	000060-0	GPI	9/5/01	211-36	S. aureus	071201F257401-7	19/2
Comments: ~~oxidase (+)~~ EE RS 9/11/01 catalase (+) coagulase (+)							
9/11/01 RS	000061-0	GPI	9/5/01	211-36	S. aureus	071201F257401-7	28/2
Comments: ~~oxidase (+)~~ EE RS 9/11/01 catalase (+) coagulase (+)							
9/11/01 RS	000062-0	GNI+	9/6/01	211-36	P. aeruginosa	071201F257401-7	50/2
Comments: oxidase (+)							
9/11/01 RS	000063-0	GNI+	9/6/01	211-36	P. aeruginosa	071201F257401-7	19/2
Comments: oxidase (+)							
9/11/01 RS	000064-0	GNI+	9/6/01	211-36	P. aeruginosa	071201F257401-4	16/2
Comments: oxidase (+)							

* Indicate the Vitek card type as GP (Gram Positive card), GNI+ (Gram Negative card), or B (Bacillus card)
\+ Indicate the Use Dilution Test carrier tube the culture originated from (1-60, primary or secondary)
\# The Vitek number appears on the Vitek report printout.

SOP QC-16-00 Form1.wpd

VITEK Microbe Identification Log
OPP/Microbiology Laboratory

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TEST Hoac use-Dilution

VITEK CONFIRMATION RECORD LOG SHEET

Date/Init.	Vitek No.#	Card*	Test Date	Product Reg. No.	Test Organism	Sample No.	Source+
9/11/01 NS	000065-0	GNI+	9/6/01	211-36	P. aeruginosa	071201F257401-4	6/2
Comments: Oxidase (+)							
9/11/01 NS	000066-0	GNI+	9/6/01	211-36	P. aeruginosa	071201F257401-4	5/2
Comments: oxidase (+)							
9/11/01 NS	000067-0	GNI+	9/6/01	211-36	P. aeruginosa	071201F257401-1	12/2
Comments: oxidase (+)							
9/14/01 NS	000068-0	GNI+	9/6/01	211-36	P. aeruginosa	071201F257401-4	6/2
Comments: oxidase (+)							
[redacted]							
Comments: [redacted]							
[redacted]							
Comments: [redacted]							
	000071-0						
Comments:							
	000072-0						
Comments:							

* Indicate the Vitek card type as GP (Gram Positive card), GNI+ (Gram Negative card), or B (Bacillus card)
\+ Indicate the Use Dilution Test carrier tube the culture originated from (1-60, primary or secondary)
\# The Vitek number appears on the Vitek report printout.

SOP QC-16-00 Form1.wpd

Vitek ID: 000060-0 (D1-01) Catalase + Coagulase +
Type: Gram Positive Identification Card (GPI)
Status: Final
Elapsed Time: 9 hours
Organism: Staphylococcus aureus
Bionumber: 7612503004 1

PB +	BAC +	OPT +	HCS -	6NC +	10B +
40B +	ESC -	ARG -	URE -	TZR +	NOV -
DEX +	LAC -	MAN +	RAF -	SAL -	SOR -
SUC +	TRE +	ARA -	PYR -	PUL -	INU -
MEL -	MLZ -	CEL -	RIB -	XYL -	CAT +
BH/CO +					

99 % Staphylococcus aureus

Wait for Nothing

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TEST AOAC Use-Dilution

Date: 09/11/2001 18:29:50
WSVTK-R07.01

bioMerieux Vitek
Automatic Vitek Lab Report

Vitek ID: 000061-0 (D1-02) Catalase + Coagulase +
Type: Gram Positive Identification Card (GPI)
Status: Final
Elapsed Time: 9 hours
Organism: Staphylococcus aureus
Bionumber: 76125030041

PB +	BAC +	OPT +	HCS -	6NC +	10B +
40B +	ESC -	ARG -	URE -	TZR +	NOV -
DEX +	LAC -	MAN +	RAF -	SAL -	SOR -
SUC +	TRE +	ARA -	PYR -	PUL -	INU -
MEL -	MLZ -	CEL -	RIB -	XYL -	CAT +
BH/CO +					

99 % Staphylococcus aureus

Wait for Nothing

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TEST AOAC Use-Dilution

Vitek ID: 000062-0 (D1-03) Oxidase +
Type: Gram Negative Identification Card (GNI+)
Status: Final
Elapsed Time: 4 hours
Organism: Pseudomonas aeruginosa
Bionumber: 71602000440

DP3 +	OFG +	GC +	ACE +	ESC -	PLI -
URE -	CIT +	MAL +	TDA -	PXB -	LAC -
MLT -	MAN +	XYL -	RAF -	SOR -	SUC -
INO -	ADO -	COU -	H2S -	ONP -	RHA -
ARA -	GLU -	ARG +	LYS -	ORN -	OXI +
TLA -					

99 % Pseudomonas aeruginosa
<1 % Pseudomonas fluorescens/putida
See Technical Bulletin, note 11.

Wait for Nothing

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TEST AOAC Use-Dilution

Vitek ID: 000063-0 (D1-04) Oxidase +
Type: Gram Negative Identification Card (GNI+)
Status: Final
Elapsed Time: 5 hours
Organism: Pseudomonas aeruginosa
Bionumber: 71602000440

DP3 +	OFG +	GC +	ACE +	ESC -	PLI -
URE -	CIT +	MAL +	TDA -	PXB -	LAC -
MLT -	MAN +	XYL -	RAF -	SOR -	SUC -
INO -	ADO -	COU -	H2S -	ONP -	RHA -
ARA -	GLU -	ARG +	LYS -	ORN -	OXI +
TLA -					

99 % Pseudomonas aeruginosa
<1 % Pseudomonas fluorescens/putida
See Technical Bulletin, note 11.

Wait for Nothing

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TEST AOAC Use-Dilution

Vitek ID: 000064-0 (D1-05) Oxidase +
Type: Gram Negative Identification Card (GNI+)
Status: Final
Elapsed Time: 5 hours
Organism: Pseudomonas aeruginosa
Bionumber: 71602000440

DP3 +	OFG +	GC +	ACE +	ESC -	PLI -
URE -	CIT +	MAL +	TDA -	PXB -	LAC -
MLT -	MAN +	XYL -	RAF -	SOR -	SUC -
INO -	ADO -	COU -	H2S -	ONP -	RHA -
ARA -	GLU -	ARG +	LYS -	ORN -	OXI +
TLA -					

99 % Pseudomonas aeruginosa
<1 % Pseudomonas fluorescens/putida
See Technical Bulletin, note 11.

Wait for Nothing

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TEST AOAC Use-Dilution

Vitek ID: 000065-0 (D1-06) Oxidase +
Type: Gram Negative Identification Card (GNI+)
Status: Final
Elapsed Time: 12 hours
Organism: Unidentified Organism
Bionumber: 71777610541

UNIDENTIFIED ORGANISM

DP3 +	OFG +	GC +	ACE +	ESC -	PLI -
URE +	CIT +	MAL +	TDA +	PXB +	LAC +
MLT +	MAN +	XYL +	RAF -	SOR +	SUC +
INO +	ADO -	COU -	H2S -	ONP -	RHA -
ARA +	GLU -	ARG +	LYS -	ORN -	OXI +
TLA +					

Wait for Nothing

Vitek ID: 000066-0 (D1-07) Oxidase +
Type: Gram Negative Identification Card (GNI+)
Status: Final
Elapsed Time: 5 hours
Organism: Pseudomonas aeruginosa
Bionumber: 7160200044C

DP3 +	OFG +	GC +	ACE +	ESC -	PLI -
URE -	CIT +	MAL +	TDA -	PXB -	LAC -
MLT -	MAN +	XYL -	RAF -	SOR -	SUC -
INO -	ADO -	COU -	H2S -	ONP -	RHA -
ARA -	GLU -	ARG +	LYS -	ORN -	OXI +
TLA -					

99 % Pseudomonas aeruginosa
<1 % Pseudomonas fluorescens/putida
See Technical Bulletin, note 11.

Wait for Nothing

bioMerieux Vitek
Automatic Vitek Lab Report

Vitek ID: 000067-0 (D1-08) Oxidase +
Type: Gram Negative Identification Card (GNI+)
Status: Final
Elapsed Time: 5 hours
Organism: Pseudomonas aeruginosa
Bionumber: 7160200440

DP3 +	OFG +	GC +	ACE +	ESC -	PLI -
URE -	CIT +	MAL +	TDA -	PXB -	LAC -
MLT -	MAN +	XYL -	RAF -	SOR -	SUC -
INO -	ADO -	COU -	H2S -	ONP -	RHA -
ARA -	GLU -	ARG +	LYS -	ORN -	OXI +
TLA -					

99 % Pseudomonas aeruginosa
<1 % Pseudomonas fluorescens/putida
See Technical Bulletin, note 11.

Wait for Nothing

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TEST AOAC Use-Dilution

Date: 09/14/2001 13:16:06 bioMerieux Vitek
WSVTK-R07.01 Automatic Vitek Lab Report

Vitek ID: 000068-0 (C1-01) Oxidase +
Type: Gram Negative Identification Card (GNI+)
Status: Final
Elapsed Time: 5 hours
Organism: Pseudomonas aeruginosa
Bionumber: 7160200440

DP3 +	OFG +	GC +	ACE +	ESC -	PLI -
URE -	CIT +	MAL +	TDA -	PXB -	LAC -
MLT -	MAN +	XYL -	RAF -	SOR -	SUC -
INO -	ADO -	COU -	H2S -	ONP -	RHA -
ARA -	GLU -	ARG +	LYS -	ORN -	OXI +
TLA -					

>99 % Pseudomonas aeruginosa
<1 % Pseudomonas fluorescens/putida
See Technical Bulletin, note 11.

Wait for Nothing

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TEST AOAC Use-Dilution

Worksheet for Recording Gram Stain and Acid Fast Reactions
OPP Microbiology Laboratory
TB Phene Epa Reg # 211-36 Test date 9/5/01
Sample 071201F257401-7

Slide ID: RS-1 Test: UDT-Ja Product: TB Phene from 9/5/01 Date: 9/7/01 Initials: RS	Source/Tube No. 401-7 # 19/2 Results: GPC	Source/Tube No. 401-7 # 28/2 Results: GPC	Source/Tube No. Results:

Slide ID: Test: Product: Date: Initials:	Source/Tube No. Results:	Source/Tube No. Results:	Source/Tube No. Results:

Slide ID: Test: Product: Date: Initials:	Source/Tube No. Results:	Source/Tube No. Results:	Source/Tube No. Results:

AF+ =Acid fast positive
GPC =Gram positive cocci
GNR =Gram negative rod

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TEST AOAC Use-Dilution

Worksheet for Recording Gram Stain and Acid Fast Reactions

OPP Microbiology Laboratory

T.B. Phene EPA Reg #211-36 Test date 9/6/01

EE RS 10.5.01

Sample 071201F257401-1

Slide ID: RS-1 Test: UDT-Pa of 9/6/01 Product: TB Phene A01-1 Date: 9/10/01 Initials: RS	Source/Tube No. 12/2 Results: GNR	Source/Tube No. Results:	Source/Tube No. Results:

Sample 071201F257401-4

Slide ID: RS-2 Test: UDT-Pa of 9/6/01 Product: TB Phene A01-4 Date: 9/10/01 Initials: RS	Source/Tube No. 5/2 Results: GNR	Source/Tube No. 6/2 Results: GNR	Source/Tube No. 16/2 Results: GNR

Sample 071201F257401-7

Slide ID: RS-3 Test: UDT-Pa of 9/6/01 Product: TB Phene A01-7 Date: 9/10/01 Initials: RS	Source/Tube No. 19/2 Results: GNR	Source/Tube No. 50/2 Results: GNR	Source/Tube No. Results: ~~GNR~~ EE RS 9/20/01

AF+ =Acid fast positive
GPC =Gram positive cocci
GNR =Gram negative rod

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TEST AOAC Use-Dilution

10.3 Table 1. Typical Growth Characteristics of *P. aeruginosa, S. aureus* and *M. bovis* (BCG) (see ref. 15.5, 15.6 and 15.15).

	P. aeruginosa	*S. aureus*	*M. bovis* (BCG)
Gram rxn.	negative	positive	positive
Acid Fast rxn.	NA	NA	Acid Fast
Typical Growth Characteristics on Media			
Growth on Mannitol salts agar	NA	circular, small, yellow colonies, agar turning flourescent yellow	NA
Growth on Pseudosel agar	circular, small, initially opaque, turning flourescent green over time; agar flourescent yellowish green	NA	NA
Growth on Middlebrook 7H9	NA	NA	rough, raised, thick colonies with a nodular or wrinkled surface and an irregular thin margin, off-white to faint buff, or even yellow
Growth on TSA agar	flat, opaque to off -white, round spreading, 2-4mm in diameter	small, circular, yellow glistening, 1-2 mm in diameter	
Typical Microscopic Characteristics			
Cell dimensions	0.5-1.0 μm in diameter by 1.5-5.0 μm in length	0.5-1.5 μm in diameter	0.3-0.6 μm in diameter by 1-4 μm in length
Cell appearance	straight or slightly curved rods, single polar flagella, rods formed in chains	spherical, occurring singly, in pairs and tetrads, sometimes forming irregular clusters	rods, straight or slightly curved, occurring singly and in occasional threads

Laboratory Chain-of-Custody Form
OPP Microbiology Laboratory

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REG. NO. 211-36
TEST Hard use-dilution

Laboratory Chain-of-Custody Form

Product Information:
EPA Reg. #: 211-36
Product Name: TB Phenol Disinfectant
Sample #: 071201F257401-1 and -2
Lot #: 04041007
Date Received: 7-16-01

Product Disposal Information:
Date of Disposal:
Sample Custodian Initials:
Amount Disposed:
Reason for Disposal:

Date/Time Removed	Sample Custodian Initials	Removed From	Purpose of Removal	Amount Used (ml)	Returned To	Sample Custodian Initials	Date/Time Returned
7.24.01/2:00 pm	MC	D204	Sterility Assessment (-1)	10mL	D204	MC	7.24.01 3:45 pm
8-8-01/2:50 pm	SH	D204	Preparation of the 28 day use dilution	25mL	D204	SH	8-8-01/ 3:45 PM
8-9-01/ 1:30 PM	SH	D204	Preparation of the 28 day use dilution	25mL	D204	SH	8-9-01/ 2:15 PM
8-14-01/ 9:15 AM	SH	D204	Use dilution test	30mL	D204	SH	~~8-14-01~~ 9:35 AM
8-15-01 9:00 AM	SH	D204	use dilution test	30mL	D204	SH	8-15-01 10:15 AM
9-5-01 10:30 am	MC	D204	Use dilution test on 28-day old dilution	~650 mL of dilution prepared 8-8-01	Remainder	Discarded	NA
9-5-01 3:15 pm	MC	D204	Sterility assessment of 28-day old dilution	~10 mL of dilution prepared 8-9-01	D204	MC	9-5-01 4:30 pm
9-6-01 9:00 am	RS	D204	Use dilution test of 8-9-01 preparation	650 mL of dilution prepared 8-9-01	Ohio product was disposed after completion of the test		RS 9/6/01
	Refer to	media	prep	sheet	for	disposal	information RS 9/18/01

EE SH 8-14-01
8-14-01

~ = approximately mc 9/5/01
n/t = not applicable mc 9/5/01

Chain-of-Custody Seal Log
OPP Microbiology Laboratory

Chain-of-Custody Seal Log

Product Information:
Product EPA Reg. #: 211-36 Product Name: TB Phene Disinfectant
Sample #: 071201F257401-1 and -2
Date Product Received: 7/16/01

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REG. NO. 211-36
TEST HORC Use-Dilution

Date/Initials	Seals Below (1 seal per row)
7.24.01/MC	AGENCY; SAMPLE NO. 071201F257401-1; DATE 7/12/01; SIGNATURE Mary C Boutz; PRINT NAME AND TITLE (Inspector, Analyst or Technician) C Boutz / ES II; SEAL BROKEN BY MC; DATE 7.24.01; EPA FORM 7500-2 (R7-75)
8-8-01 SH	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SAMPLE SEAL; SAMPLE NO. 071201F257401-1; DATE 7.24.01; SIGNATURE Michele Cothrill; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Michele Cothrill, Analyst; SEAL BROKEN BY SH; DATE 8-8-01; EPA FORM 7500-2(R7-75)
8-9-01 SH	STATES PROTECTION AGENCY SAMPLE SEAL; SAMPLE NO. 071201F257401-1; DATE 8-8-01; SIGNATURE Stephen Tomasino; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Stephen Tomasino, Team Leader; SEAL BROKEN BY SH; DATE 8-9-01; EPA FORM 7500-2(R7-75)
8-14-01 SH	STATES PROTECTION AGENCY SAMPLE SEAL; SAMPLE NO. 071201F257401-1; DATE 8-9-01; SIGNATURE Stephen Tomasino; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Stephen Tomasino, Team Leader; SEAL BROKEN BY SH; DATE 8-14-01; EPA FORM 7500-2(R7-75)

e.e. SH 10-10-01

Seal broken on 8-9-01 SH

COC-01Form3.wpd

Chain-of-Custody Seal Log
OPP Microbiology Laboratory

Chain-of-Custody Seal Log

Product Information:
Product EPA Reg. #: 211-36
Sample #: 071201F257401-1 and -2
Date Product Received: 7/16/01

Product Name: TB Phene Disinfectant

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REG. NO. 211-36
TEST AOAC Use-Dilution

Reserve entries of 8-15-01

Date/Initials	Apply Seals Below (1 seal per row)
8-15-01 SF	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SAMPLE SEAL [illegible] SAMPLE NO. 071201F257401-1 SIGNATURE [illegible] DATE 8-14-01 PRINT NAME AND TITLE (Inspector, Analyst or Technician) Stephen Masino Team Leader SEAL BROKEN BY [illegible] DATE 8-15-01 EPA FORM 7500-2(R7-75)
9-5-01 MC	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SAMPLE SEAL P080801-04 SAMPLE NO. 071201F257401-1 DATE 8-8-01 SIGNATURE K. Verma 3:30PM PRINT NAME AND TITLE (Inspector, Analyst or Technician) Kiran Verma / Analyst SEAL BROKEN BY MC DATE 9-5-01 EPA FORM 7500-2(R7-75)
9-5-01 MC	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SAMPLE SEAL P080901-02 SAMPLE NO. 071201F257401-1 DATE 8-9-01 SIGNATURE K. Verma PRINT NAME AND TITLE (Inspector, Analyst or Technician) Kiran Verma / Analyst SEAL BROKEN BY MC DATE 9-5-01 EPA FORM 7500-2(R7-75)
9-6-01 RS	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SAMPLE SEAL P080901-02 SAMPLE NO. 071201F257401-1 DATE 9-5-01 SIGNATURE Michele Cottrill PRINT NAME AND TITLE (Inspector, Analyst or Technician) Michele Cottrill, Analyst SEAL BROKEN BY RS DATE 9/6/01

Seals for product diluted and stored for 28 days prior to use dilution testing. MC 9-19-01

COC-01Form3.wpd

Laboratory Chain-of-Custody Form
OPP Microbiology Laboratory

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REG. NO. 211-36
TEST Use-Dilution

Laboratory Chain-of-Custody Form

Product Information:
EPA Reg. #: 211-36
Product Name: TB Phene Disinfectant
Sample #: 071201F257401-4 and -5
Lot #: 06281002
Date Received: 7-16-01

Product Disposal Information:
Date of Disposal:
Sample Custodian Initials:
Amount Disposed:
Reason for Disposal:

Date/Time Removed	Sample Custodian Initials	Removed From	Purpose of Removal	Amount Used (ml)	Returned To	Sample Custodian Initials	Date/Time Returned
7.24.01/2:00 pm	MC	D204	Sterility Assessment (-4)	10mL	D204	MC	7.24.01 3:45pm
8-8-01/2:50 PM	St	D204	Preparation of the 28day use dilution	25mL	D204	St	8-8-01/ 3:45PM
8-9-01/ 1:30PM	St	D204	Preparation of the 28day Use dilution	25mL	D204	St	8-9-01/ 2:15PM
8-14-01 9:15AM	St	D204	Use Dilution test	30mL	D204	St	8-14-01 9:35AM
8-15-01 9:00AM	St	D204	Use dilution test	30mL	D204	St	8-15-01 10:15AM
9-5-01 10:30am	MC	D204	Use dilution test on 28-day old dilution	~650 mL of dilution prepared 8-8-01	Remainder Discarded		NA
9-5-01 3:15pm	MC	D204	Sterility Assessment of 28-day old dilution	~10mL of dilution prepared 8-9-01	D204	MC	9-5-01 ~~4~~ 4:30pm
9-6-01 9:00am	RS	D204	Use dilution test of 8-9-01 preparation	650mL of dilution prepared 8-9-01	This preparation was disposed of after completion of the test		RS 9/6/01
Refer to media prep sheet for disposal information RS 9/18/01							
9-19-01 9:10am	MC	D204	CTB Test (-4)	20mL	D204	MC	9-19-01 10:30am

E.E. MC 9-5-01

~ = approximately mc 9/5/01
N.A. = not applicable mc 9/5/01

Chain-of-Custody Seal Log
OPP Microbiology Laboratory

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REG. NO. 211-36
TEST Hope use-Dilution

Chain-of-Custody Seal Log

Product Information:
Product EPA Reg. #: 211-36
Product Name: JB Phene Disinfectant
Sample #: 071201F257401-4 and -5
Date Product Received: 7/16/01

Date/Initials	Apply Seals Below (1 seal per row)
7.24.01/MC	SAMPLE NO. 071201F257401-4 DATE 7/17/01; SIGNATURE Gary C Bouty; PRINT NAME AND TITLE (Inspector, Analyst or Technician) G Bouty / ES II; SEAL BROKEN BY MC DATE 7.24.01; EPA FORM 7500-2 (R7-75)
8-8-01 St	STATES ROTECTION AGENCY SAMPLE SEAL; SAMPLE NO. 071201F257401-4 DATE 7.24.01; SIGNATURE Michele Cottrill; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Michele Cottrill, Tr / Ast; SEAL BROKEN BY St DATE 8-8-01; EPA FORM 7500-2(R7-75)
8-9-01 St	SAMPLE NO. 071201F257401-4 DATE 8-8-01; SIGNATURE Stephen Tomasino; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Stephen Tomasino; SEAL BROKEN BY St DATE 8-9-01; EPA FORM 7500-2(R7-75)
8-14-01 St	TATES TECTION AGENCY MPLE SEAL; SAMPLE NO. 071201F257401-4 DATE 8-9-01; SIGNATURE Stephen Tomasino; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Stephen Tomasino, Team Leader; SEAL BROKEN BY St DATE 8-14-01; EPA FORM 7500-2(R7-75)

COC-01Form3.wpd

Chain-of-Custody Seal Log
OPP Microbiology Laboratory

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REG. NO. 211-36
TEST Hepac Use-Dilution

Chain-of-Custody Seal Log

Product Information:
Product EPA Reg. #: 211-36
Sample #: 071201F257401-4 and -5
Date Product Received: 7/16/01
Product Name: TB Phene Disinfectant

Date/Initials	Apply Seals Below (1 seal per row)
8-15-01	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SEAL; 071201F257401-4; DATE 8-14-01; SIGNATURE [illegible]; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Kazu Tanasino Team Leader; SEAL BROKEN BY; DATE 8-15-01; EPA FORM 7500-2(R7-75)
9-5-01 MC	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SAMPLE SEAL P080801-05; SAMPLE NO. 071201F257401-4; DATE 8-8-01; SIGNATURE K. Verma; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Kiran Verma / Analyst; SEAL BROKEN BY MC; DATE 9-5-01; EPA FORM 7500-2(R7-75)
9-5-01 MC.	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SAMPLE SEAL P-080901-03; SAMPLE NO. 071201F257401-4; DATE 8-9-01; SIGNATURE K. Verma; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Kiran Verma / Analyst; SEAL BROKEN BY MC; DATE 9-5-01; EPA FORM 7500-2(R7-75)
9-6-01 RS	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SAMPLE SEAL P-080901-04 E.E. MC 9/5/01; SAMPLE NO. 071201F257401-4; DATE 9-5-01; SIGNATURE Michele Cottrill; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Michele Cottrill, Analyst; SEAL BROKEN BY RS; DATE 7/6/01; EPA FORM 7500-2(R7-75)

Seals for product diluted and stored for 28 days prior to Use Dilution testing. MC 9-19-01

COC-01Form3.wpd

Chain-of-Custody Seal Log
OPP Microbiology Laboratory

Chain-of-Custody Seal Log

Product Information:
Product EPA Reg. #: 211-36
Product Name: TB Phene Disinfectant
Sample #: 071201F257401-4 and -5
Date Product Received: 7/16/01

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REG. NO. 211-36
TEST

Date/Initials	Apply Seals Below (1 seal per row)
9-19-01/MC	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SAMPLE SEAL — SAMPLE NO. 071201F257401-4 — DATE 8-15-01 — SIGNATURE Stephen Tomasino — PRINT NAME AND TITLE (Inspector, Analyst or Technician) Stephen Tomasino, Team Leader — SEAL BROKEN BY MC — DATE 9-19-01 — EPA FORM

COC-01Form3.wpd

Laboratory Chain-of-Custody Form
OPP Microbiology Laboratory

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REG. NO. 211-36
TEST Use-Dilution

Laboratory Chain-of-Custody Form

Product Information:
EPA Reg. #: 211-36
Product Name: TB Phene Disinfectant
Sample #: 071201F257401-7 and -8
Lot #: 1228 007
Date Received: 7-16-01

Product Disposal Information:
Date of Disposal:
Sample Custodian Initials:
Amount Disposed:
Reason for Disposal:

Date/Time Removed	Sample Custodian Initials	Removed From	Purpose of Removal	Amount Used (ml)	Returned To	Sample Custodian Initials	Date/Time Returned
7.24.01/2:00 pm	MC	D204	Sterility Assessment (-7)	10mL	D204	MC	7.24.01 3:45pm
8-8-01/2:50 PM	SF	D204	Preparation of the 28 day use dilution	25mL	D204	SF	8-8-01/ 3:45 PM
8-9-01/ 1:30PM	SF	D204	Preparation of the 28 day use dilution	25mL	D204	SF	8-9-01/ 2:15PM
8-14-01/ 9:15AM	SF	D204	Use-dilution test	30mL	D204	SF	8-14-01 9:35AM
8-15-01 9:00AM	SF	D204	Use dilution test	30mL	D204	SF	8-15-01 10:15AM
9-5-01 10:30am	MC	D204	Use dilution test on 28-day old dilution	~650 mL of dilution prepared 8-8-01	Remainder Discarded		NA
9-5-01 3:15pm	MC	D204	Sterility Assessment of 28-day old dilution	~10mL of dilution prepared 8-9-01	D204	MC	9-5-01 4:30pm
9-6-01 9:00am	RS	D204	Use dilution test of 8-9-01 preparation	650mL of dilution prepared 8-9-01	This product was disposed of after completion of the test RS		9/6/01
Refer to media prep sheet for disposal information RS 9/18/01							
9-19-01/9:10am	MC	D204	CTB Test (-7)	20mL	D204	MC	9-19-01 10:30am

~ = approximately mc 9/5/01
/ = Not Applicable mc 9/5/01

Chain-of-Custody Seal Log
OPP Microbiology Laboratory

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REG. NO. 211-36
TEST Dilution

Chain-of-Custody Seal Log

Product Information:
Product EPA Reg. #: 211-36
Product Name: TB Phene Disinfectant
Sample #: 071201F257401-7 and -8
Date Product Received: 7/16/01

Date/Initials	Seals Below (1 seal per row)
7.24.01/MC	SAMPLE NO. 071201F257401-7 DATE 7/12/01; SIGNATURE Gary E Boutz; PRINT NAME AND TITLE (Inspector, Analyst or Technician) G. Boutz / ES II; SEAL BROKEN BY MC; DATE 7.24.01; EPA FORM 7500-2
8-8-01 St	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY ENVIRONMENTAL SAMPLE SEAL; SAMPLE NO. 071201F257401-7 DATE 7.24.01; SIGNATURE Michele Cottrell; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Michele Cottrell, Analyst; SEAL BROKEN BY St; DATE 8-8-01; EPA FORM 7500-2(R7-75)
8-9-01 St	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; SAMPLE NO. 071201F257401-7 DATE 8-9-01; SIGNATURE Stephen Tomasino; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Stephen Tomasino; SEAL BROKEN BY St; DATE 8-9-01; EPA FORM 7500-2(R7-75)
8-14-01 St	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; SAMPLE NO. 071201F257401-7 DATE 8-9-01; SIGNATURE Stephen Tomasino; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Stephen Tomasino, Team Leader; SEAL BROKEN BY St; DATE 8-14-01; EPA FORM 7500-2(R7-75)

COC-01Form3.wpd

Chain-of-Custody Seal Log
OPP Microbiology Laboratory

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REG. NO. 211-36
TEST AOAC Use Dilution

Chain-of-Custody Seal Log

Product Information:
Product EPA Reg. #: 211-36
Sample #: 071201F257401-7 and -8
Date Product Received: 7/16/01
Product Name: TB Phenol Disinfectant

Date/Initials	Apply Seals Below (1 seal per row)
8-15-01 ST	AGENCY; SAMPLE NO. 071201F257401-7; DATE 8-14-01; SIGNATURE Stephen Tomasino; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Stephen Tomasino, Team Leader; SEAL BROKEN BY ST; DATE 8-15-01; EPA FORM 7500-2(R7-75)
9-5-01 MC	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SAMPLE SEAL P-080801-06; SAMPLE NO. 071201F257401-7; DATE 8-8-01; SIGNATURE K. Verma; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Kiran Verma / Analyst; SEAL BROKEN BY MC; DATE 9-5-01; EPA FORM 7500-2(R7-75)
9-5-01 MC	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SAMPLE SEAL -080901-04; SAMPLE NO. 071201F257401-7; DATE 8-9-01; SIGNATURE Kiran Verma; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Kiran Verma; SEAL BROKEN BY MC; DATE 9-5-01; EPA FORM 7500-2(R7-75)
9-6-01 MS	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SAMPLE SEAL P-080901-04; SAMPLE NO. 071201F257401-7; DATE 9-5-01; SIGNATURE Michele Cottrill; PRINT NAME AND TITLE (Inspector, Analyst or Technician) Michele Cottrill, Analyst; SEAL BROKEN BY MS; DATE 9-6-01; EPA FORM 7500-2

Seals for product diluted and stored for 28 days prior to use dilution testing. MC 9-9-01

EE MS 10.10.01 Seal broken on 9/16/01

EE MS 10.10.01

COC-01Form3.wpd

Chain-of-Custody Seal Log
OPP Microbiology Laboratory

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TEST AOAC Use-Dilution

Chain-of-Custody Seal Log

Product Information:
Product EPA Reg. #: 211-36
Sample #: 071201F257401-7 and -8
Date Product Received: 7/16/01

Product Name: TB Phene Disinfectant

Date/Initials	Apply Seals Below (1 seal per row)
9-19-01 / MC	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY OFFICIAL SAMPLE SEAL — SAMPLE NO. 071201F257401-7 — DATE 8-15-01 — SIGNATURE Stephen Tomasino — PRINT NAME AND TITLE (Inspector, Analyst or Technician) Stephen Tomasino, TEAM Leader — SEAL BROKEN BY MC — DATE 9-19-01 — EPA FORM 7500-2(R7-75)

COC-01Form3.wpd

Shipping and Receiving Record for Disinfectant Product Samples Form
OPP Microbiology Laboratory

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REG. NO. 211-36
TEST AOAC Use-Dilution

Shipping and Receiving Record for Disinfectant Product Samples

Loading Dock Personnel (Date/Initials): *	Loading Dock Personnel (Date/Initials): *
Shipping Container # 1 of 2	Shipping Container # 2 of 2
Date and Time Received: 7/16/01 9:15 am	Date and Time Received: 7/16/01 9:15 am
Received By: Iashia Glover	Received By: Iashia Glover
Received From: Sandy Cuffel, KS Dept. of Ag.	Received From: Sandy Cuffel KS Dept. of Ag.
Type of Delivery: Fedex OVERNIGHT	Type of Delivery: Fedex OVERNIGHT
Tracking Number (if available): 792426664072	Tracking Number (if available): 7916 1222 5919
Sample Custodian (Date/Initials): 7-16-01 st	Sample Custodian (Date/Initials): 7-16-01 / st
Condition of Primary Shipping Container: Good	Condition of Primary Shipping Container: Good
Product Name(s): T.B. Phene	Product Name(s): T.B. Phene
EPA Reg. No.(s): 211-36	EPA Reg. No.(s): 211-36
Sample Numbers: 071201F257401-2 071201F257401-5 071201F257401-8	Sample Numbers: 071201F257401-1 071201F257401-4 071201F257401-7

* Entry omissions by Iashia Glover on 7-16-01. Currently unavailable to fill in the fields.
st 9-18-01

COC-01Form1.wpd

HISTORY OF OFFICIAL SAMPLE		1. SAMPLE NUMBER 071201F257401-1	2. REGISTRATION NUMBER 211-36
		3. PRODUCT T.B. Phene	
4. LABORATORY	OPP Microbiology Laboratory		
5. DATE RECEIVED	7-16-01		
6. RECEIVED BY	Stephen Tomasino (entered 10-9-01)		
7. RECEIVED FROM	Tashia Glover / Sandy Cuffel (KS Dept. of Ag)		
8. SENT VIA	Fed Ex		
9. SAMPLE CONDITION	Good		
10. CONDITION OF SEALS	Good		
11. SEALED BY	Gary Bautz		
12. DATE SEALED	7-12-01		
13. PIECES RECEIVED	1 seal; 1-1 gal. container		
14. PLACE STORED	D204		
15. ASSIGNED BY			
16. ASSIGNED TO			
17. DELIVERED BY			
18. DATE DELIVERED			
19. NUMBER SUBS RECEIVED			
20. SUBS ANALYZED			
21. DATE SEAL BROKEN			
22. DATE RESEALED			
23. RESEALED BY			
24. PLACE STORED			
25. DATE JACKET SENT OUT			

26. REMARKS

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TEST AOAC Use-Dilution

EPA Form 3540-17 (12-73) REPLACES PR FORM 1-136 WHICH IS OBSOLETE.

HISTORY OF OFFICIAL SAMPLE		1. SAMPLE NUMBER 071201F257401-4	2. REGISTRATION NUMBER 211-36
		3. PRODUCT T.B. Phene	
4. LABORATORY	OPP Microbiology Laboratory		
5. DATE RECEIVED	7-16-01		
6. RECEIVED BY	Stephen Tomasino (entered 10-9-01)		
7. RECEIVED FROM	Tasha Glover / Sandy Cuffel (KS Dept. of Ag)		
8. SENT VIA	Fed Ex		
9. SAMPLE CONDITION	Good		
10. CONDITION OF SEALS	Good		
11. SEALED BY	Gary Bontz e.o.st 10-9-01		
12. DATE SEALED	7-12-01		
13. PIECES RECEIVED	1 seal; 1-1 gal container		
14. PLACE STORED	D204		
15. ASSIGNED BY			
16. ASSIGNED TO			
17. DELIVERED BY			
18. DATE DELIVERED			
19. NUMBER SUBS RECEIVED			
20. SUBS ANALYZED			
21. DATE SEAL BROKEN			
22. DATE RESEALED			
23. RESEALED BY			
24. PLACE STORED			
25. DATE JACKET SENT OUT			
26. REMARKS			

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TEST AOAC Use-Dilution

EPA Form 3540-17 (12-73)

REPLACES PR FORM 1-136 WHICH IS OBSOLETE.

HISTORY OF OFFICIAL SAMPLE		1. SAMPLE NUMBER 071201F257401-7	2. REGISTRATION NUMBER 211-36
		3. PRODUCT T. B. Phene	
4. LABORATORY	OPP Microbiology Laboratory		
5. DATE RECEIVED	7-16-01		
6. RECEIVED BY	Stephen Tomasino (entered 10-9-01)		
7. RECEIVED FROM	Tashia Glover / Sandy Ciffel (KS Dept of Ag)		
8. SENT VIA	Fed Ex		
9. SAMPLE CONDITION	Good		
10. CONDITION OF SEALS	Good		
11. SEALED BY	Gary Bortz		
12. DATE SEALED	7-12-01		
13. PIECES RECEIVED	1 seal; 1-1 gal. container		
14. PLACE STORED	D204		
15. ASSIGNED BY			
16. ASSIGNED TO			
17. DELIVERED BY			
18. DATE DELIVERED			
19. NUMBER SUBS RECEIVED			
20. SUBS ANALYZED			
21. DATE SEAL BROKEN			
22. DATE RESEALED			
23. RESEALED BY			
24. PLACE STORED			
25. DATE JACKET SENT OUT			
26. REMARKS			

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TEST AOAC Use-Dilution

EPA Form 3540-17 (12-73)

REPLACES PR FORM 1-136 WHICH IS OBSOLETE.

Case # 071201F257401

CHAIN OF CUSTODY RECORD
ENVIRONMENTAL PROTECTION AGENCY REGION VII

ACTIVITY LEADER(Print)	NAME OF SURVEY OR ACTIVITY	DATE OF COLLECTION (DAY / MONTH / YEAR)	SHEET
Gary Boutz	FIFRA Insp = Antimicrobial Tests	12 / 07 / 01	1 of 1

CONTENTS OF SHIPMENT EPA Registered disinfectant Products

SAMPLE NUMBER	TYPE OF CONTAINERS: CUBITAINER	1 gal BOTTLE	BOTTLE	BOTTLE	VOA SET (2 VIALS EA)	SAMPLED MEDIA: water	soil	sediment	dust	other X	RECEIVING LABORATORY REMARKS/OTHER INFORMATION (condition of samples upon receipt, other sample numbers, etc.)
	NUMBERS OF CONTAINERS PER SAMPLE NUMBER										
071201F257401-											product - collected from "sealed" case containing 4 - 1 gal jugs
#1		1									
#2		1									
~~#3~~											
#4		1									collected from 55 gal drum + into 1 gal jugs
#5		1									
#7		1									collected from 55 gal drum + into 1 gal jugs
#8		1									

Product = T.B. Phase Disinfectant = EPA Reg # 211-36

Designated recipient for samples listed here is: Dr. Stephen Tomasino

These 6 sample go to OPP Fort Meade Microbiology Lab
Samples 1+2 represent lot # 04041007 - produced 4-21-01
Samples 4+5 represent lot # 06281002 - produced 7-9-01
Samples 7+8 represent lot # 1228007 - produced 1-7-01

Samples 3, 6, + 9 are going to same location for Chemical Formulation Testing by Mark Law

DESCRIPTION OF SHIPMENT: Product - original	MODE OF SHIPMENT: Fed-X Overnight
6 PIECE(S) CONSISTING OF 2 BOX(ES)	X COMMERCIAL CARRIER: - Fed-X
ICE CHEST(S); OTHER	COURIER
	SAMPLER CONVEYED (SHIPPING DOCUMENT NUMBER)

PERSONNEL CUSTODY RECORD

RELINQUISHED BY (SAMPLER)	DATE	TIME	RECEIVED BY	REASON FOR CHANGE OF CUSTODY
Gary E Boutz (X SEALED / UNSEALED)	7/13/01		Stephen Tomasino 7-16-01 (X SEALED / UNSEALED)	Shipment to Lab for Analysis
RELINQUISHED BY (SEALED / UNSEALED)	DATE	TIME		
RELINQUISHED BY (SEALED / UNSEALED)	DATE	TIME		

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7-EPA-9262(Revised 5/85)

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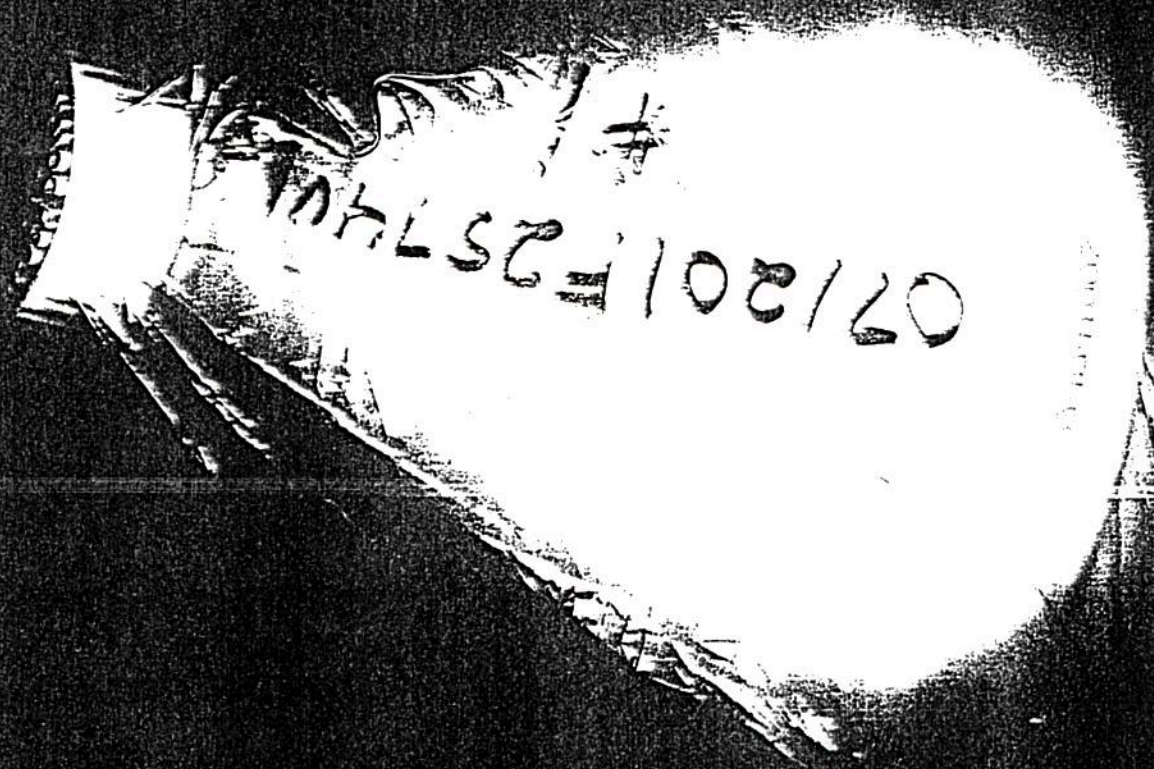

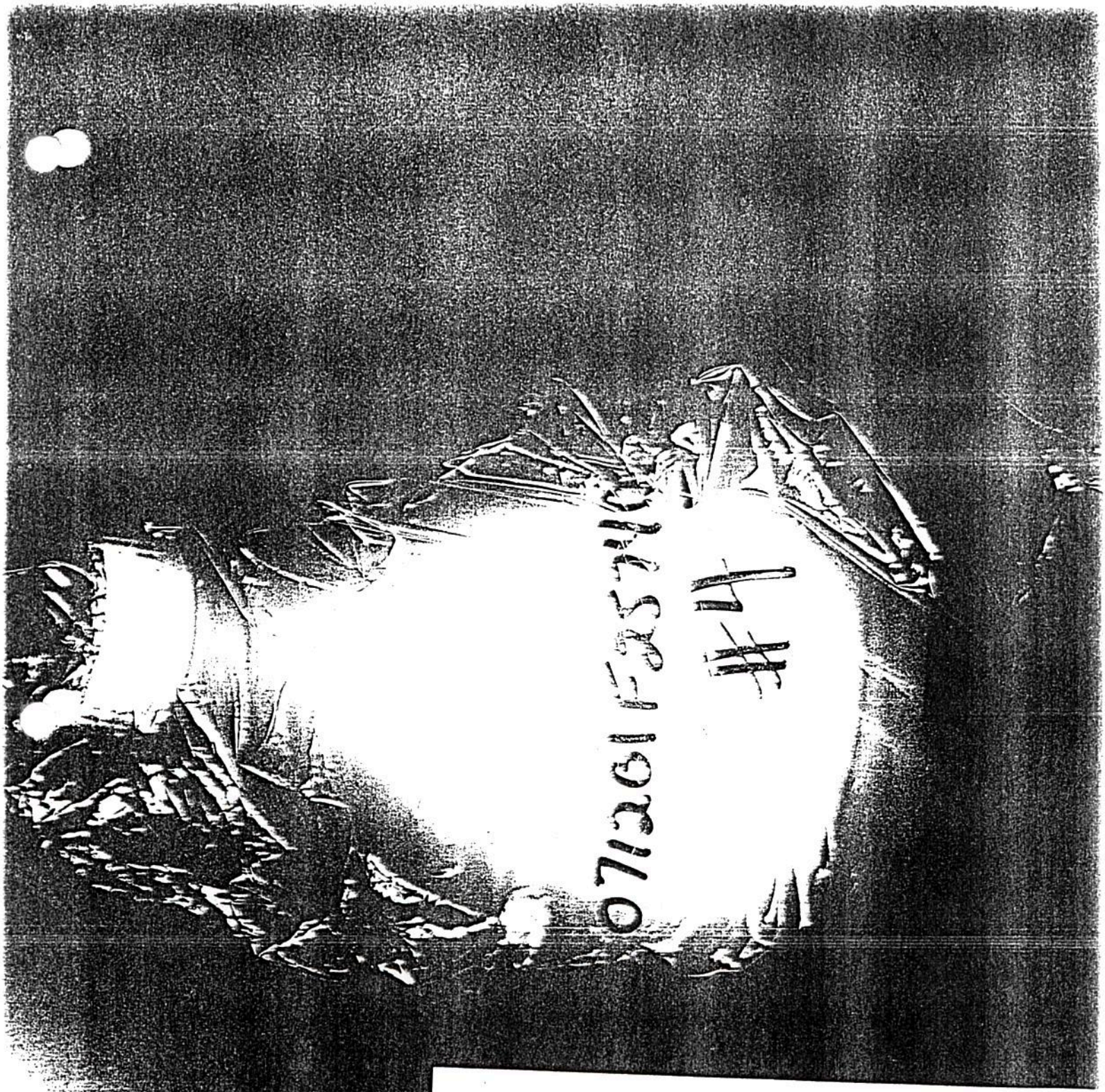

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TEST AOAC Use-Dilution

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TEST AOAC Use-Dilution

Lot 0425 1002

PHENE

GERMICIDAL DETERGENT
WITH ORGANIC SOIL TOLERANCE

Formulated for effective health care sanitation

- Pseudomonacidal
- Fungicidal
- Tuberculocidal
- *Virucidal

Active Ingredients

Sodium ortho-benzyl para-chlorophenate	4.40%
Sodium ortho-phenylphenate	2.32%
Sodium para tertiary-amylphenate	2.49%
Inert Ingredients	90.29%

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

DANGER

Keep Out of Reach of Children

EPA EST. NO. 211-41
EPA REG. NO. 211-36

P.O. Box 15276
3130 Brickenhoff Road
Kansas City, MO 64115

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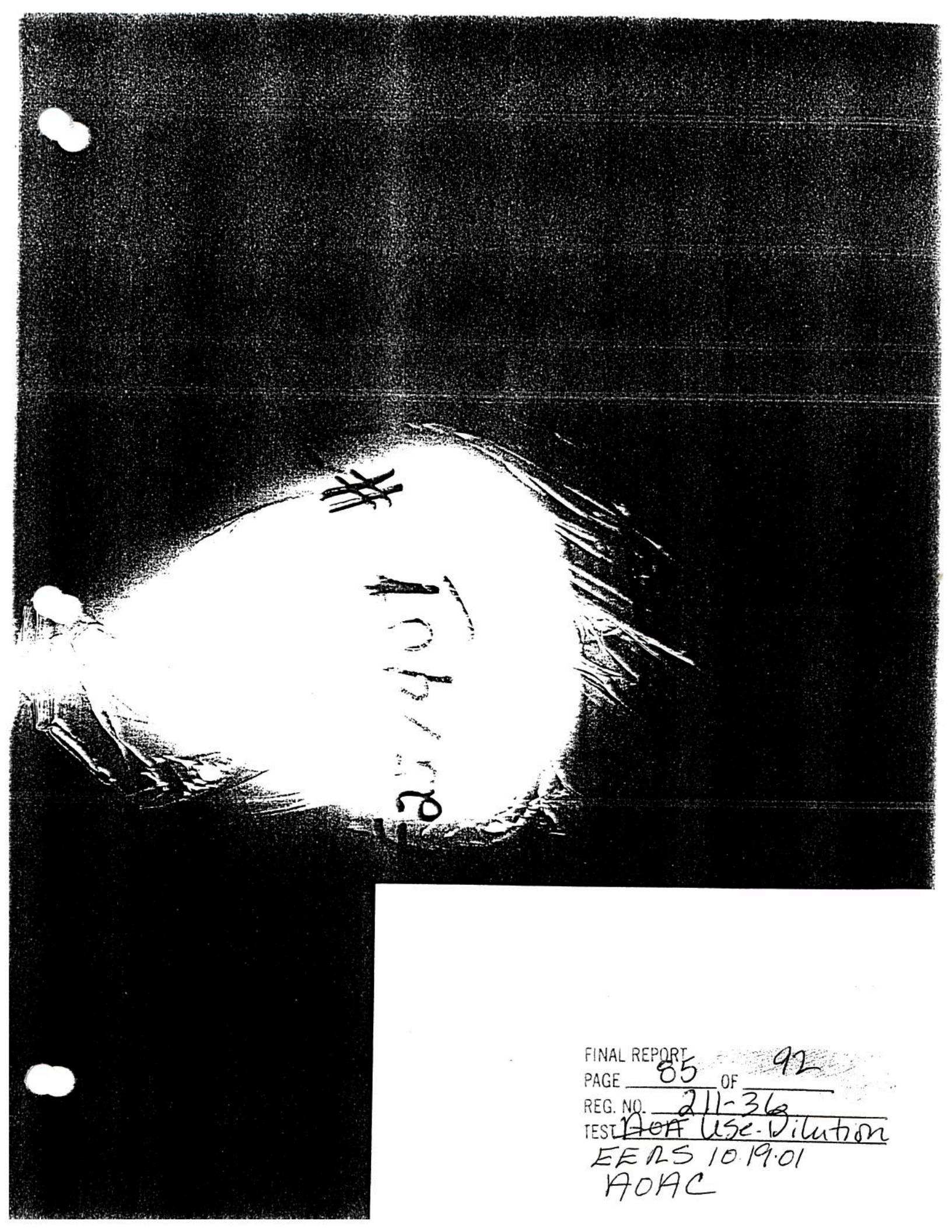
TEST AOAC-Use-Dilution



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TEST ~~AOAC~~ Use-Dilution
EERS 10.19.01
AOAC

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TEST AOAC Use-Dilution

Lot 12280007

PHENE

GERMICIDAL DETERGENT
WITH ORGANIC SOIL TOLERANCE

Formulated for effective health care sanitatio

- **Pseudomonacidal**
- **Fungicidal**
- **Tuberculocidal**
- ***Virucidal**

Active Ingredients

Sodium ortho-benzyl-para-chlorophenate	4.40%
Sodium ortho-phenylphenate	2.82%
Sodium para-tertiary-amylphenate	2.49%
Inert Ingredients	90.29%

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEME

DANGER

Keep Out of Reach of Children

EPA EST. NO. 21
EPA REG. NO. 21

RAL SOLUTIONS, INC.
P.O. Box 15276
3130 Brinkerhoff Road
Kanas City, KS 66115

T.B. PHENE

GERMICIDAL DETERGENT WITH ORGANIC SOIL TOLERANCE

Formulated for effective health care sanitat

- Pseudomonacidal - Fungicidal
- Tuberculocidal - *Virucidal

Active Ingredients

Sodium ortho-benzyl-para-chlorophenate.....4.40%
Sodium ortho-phenylphenate.....2.82%
Sodium para tertiary-amylphenate.....2.49%
Inert Ingredients.....90.29%

SEE LEFT PANEL FOR ADDITIONAL PRECAUTIONARY STATEM

DANGER

Keep Out of Reach of Children

NET CONTENTS ONE GALLON

EPA EST. NO. 21
EPA REG. NO. 21

CENTRAL SOLUTIONS, INC.

P.O. Box 15276
3130 Brinkerhoff Road
Kansas City, KS 66115

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TEST AOAC Use-Dilution

T.B. PHENE is a phosphate free, [illegible], effective germicidal detergent formulated [illegible] broad spectrum disinfection, is required in the p[illegible]nce of moderate amounts of organ[illegible] **PHENE's** multi phenolic formula is designed to clean, disinfect and deodorize [illegible] hard/male, non porous surface in one easy step. When used as directed, **T.B. PHE**[illegible] enough to kill a broad spectrum of pathogenic [illegible]cteria, yet it is mild enough to leav[illegible] effects on the surface being disinfected, when used as directed.

T.B. PHENE is recommended for use by hospitals, nursing homes, veterinary [illegible] shelters, kennels, medical emergency rooms, ambulance and patient transfer vehicle[illegible] law enforcement vehicles, prisoner holding areas, offices, funeral homes, medical and [illegible] care facilities, schools, and other establishments dedicated to controlling [illegible] cross contamination.

T.B. PHENE is an effective disinfectant, deodorant, and air freshener in patient and [illegible] utility areas, dressing rooms, hospital rooms, treatment rooms, restrooms, halls, public [illegible] classrooms.

T.B. PHENE may be used on any hard, inanimate surfaces such as walls, floors, door[illegible] frames, springs, wheelchairs, light switches, linen carts, stretcher wheels, hampers, [illegible] cleanup carts, bassinets, dressing carts, toilets, urinals, showers, bathtubs, counter to[illegible] sinks, waste containers, lockers, desks, hydrotherapy bathing units, patient transf[illegible] stainless steel, porcelain, glass, and chrome.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its [illegible]

DIRECTIONS FOR CLEANING AND DISINFECTION: For broad spectrum disinfection [illegible] negative and gram positive bacteria, including Pseudomonas aeruginosa, add 1 ounce T.[illegible] to the gallon of water. Remove heavy soil or gross filth then apply solution with a mop, [illegible] sponge, or hand pump trigger sprayer, so as to wet the surface thoroughly. Allow to rem[illegible] 10 minutes and then let air dry. Where tuberculocidal activity is required, clean the surf[illegible] application of the disinfectant solution. Allow to remain wet for 10 minutes and then let air [illegible] higher detergency is desired, increase dilution to 2 ounces per gallon of water. Prepare [illegible] solution for each use.

This product is not to be used as a terminal sterilant/high level disinfectant on any [illegible] instrument that (1) is introduced directly into the human body, either into or in [illegible] bloodstream or [illegible]ally sterile areas of the body, or (2) contacts intact mucous m[illegible] which does not ordinarily penetrate the blood barrier or otherwise enter normally steri[illegible] body. This product may be used to precleanse or decontaminate critical or semi-cri[illegible] devices prior to sterilization or high level disinfection.

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EFFICACY PERFORMANCE

The broad spectrum efficacy of T.B. PHENE has been confirmed using A.O.A.C. Protocol [illegible] of 1:128 in the presence of 5% blood serum (used to simulate organic soil body [illegible] exposure time of 10 minutes.

GERMICIDAL: T.B. PHENE is effective against the broad spectrum of Gram [illegible] pathogens as confirmed against *Salmonella choleraesuis*, *Staphylococcus* [illegible] by the AOAC Use Dilution test, in the presence of 5% organic soil fed at 20 days [illegible] time of 10 minutes.

T.B. PHENE is also effective against *Salmonella choleraesuis*, *Staphylococcus aureus* [illegible] *serratia* 28 days after dilution at 1:128 in the presence of 5% organic soil bed at 20°C [illegible] 10 minutes.

FUNGICIDAL: At 1 ounce per gallon of water, T.B. PHENE is also [illegible] *mentagrophytes*, (the athlete's foot fungus) in use areas such as shower rooms [illegible] bathmats or any other hard nonporous, inanimate environmental surfaces.

TUBERCULOCIDAL: T.B. PHENE disinfectant's effectiveness against *Mycobacterium* [illegible] demonstrated through testing using the AOAC Method "Confirmative In Vitro Test for [illegible] Activity". Where Tuberculocidal activity is required, clean the surface prior to [illegible] solution.

VIRUCIDAL: KILLS HIV-1 ON PRE-CLEANED ENVIRONMENTAL SURFACES [illegible] SOILED WITH BLOOD/BODY FLUIDS in health care settings or other [illegible] likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in [illegible] to be soiled with blood or body fluids can be associated with the potential [illegible] immunodeficiency virus Type-1 (HIV-1) (associated with AIDS)

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST [illegible] SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: Disposable gloves should be worn when cleaning [illegible] items. Hands should be washed immediately and thoroughly after gloves are [illegible] contaminated with blood or body fluids. Masks and protective eyewear or face [illegible] cleaning procedures involving blood or body fluids. Gowns or aprons should be [illegible] for protection against splashes of blood or other body fluids.

CLEANING PROCEDURE: Blood and other body fluids must be thoroughly [illegible] before application of the disinfectant. After cleaning is complete follow disinfection [illegible]

CONTACT TIME: Leave surfaces wet for 10 minutes. Let air dry.

DISPOSAL OF INFECTIOUS MATERIALS: Contaminated waste and blood and [illegible] autoclaved and disposed according to local regulations for infectious waste disposal.

Recd 7/16/01
@ 9:15
by Joshua Glover

Box 1 of 2 JH
9-20-01

PLEASE FOLD THIS SHIPPING DOCUMENT IN HALF AND PLACE IT IN A WAYBILL POUCH AFFIXED TO YOUR SHIPMENT SO THAT THE BAR-CODE PORTION OF THE LABEL CAN BE READ AND SCANNED. ***WARNING: USE ONLY THE PRINTED ORIGINAL LABEL FOR SHIPPING. USING A PHOTOCOPY OF THIS LABEL FOR SHIPPING PURPOSES IS FRAUDULENT AND COULD RESULT IN ADDITIONAL BILLING CHARGES, ALONG WITH THE CANCELLATION OF YOUR FEDEX ACCOUNT NUMBER.

FROM: Sandy Cuffel (785)296-2263
Kansas Dept of Agriculture
109 SW 9th St
3rd Floor
Topeka, KS 66612

SHIPPER'S FEDEX ACCOUNT NUMBER

FedEx
Federal Express

TO: DR STEPHEN TOMASINO (410)305-2976
OPP/MICROBIOLOGY LABORATORY
701 MAPES ROAD
ENVIRONMENTAL SCIENCE CENTER

FT MEADE, MD 20755-5350

SHIP DATE: 13JUL01
MAN-WGT: 20 LBS

REF: [redacted]

DELIVERY ADDRESS BARCODE (FEDEX-EDR)

CAD # 4162216 **PRIORITY OVERNIGHT** **MON**

BOX AA

TRK # **7924 2656 4072** FORM 0201 BWI Deliver By: 16JUL01

20755-MD-US **XB ADWA**

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Rec'd 7/16/01 @ 9:15 by Tashia Clark

Box 2 of 2
lt 9-20-01

PLEASE FOLD THIS SHIPPING DOCUMENT IN HALF AND PLACE IT IN A WAYBILL POUCH AFFIXED TO YOUR SHIPMENT SO THAT THE BAR-CODE PORTION OF THE LABEL CAN BE READ AND SCANNED.
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MAN-WGT: 20 LBS

REF: [redacted]

DELIVERY ADDRESS BARCODE (FEDEX-EDR)

CAD # 4162216 **PRIORITY OVERNIGHT** **MON**

BOX AA

TRK # **7916 1222 5919** FORM 0201 **BWI** Deliver By: 16JUL01

20755-MD-US **XB ADWA**

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PACKAGE RECEIVING LOG

DATE	SHIPPING CO.	VENDOR	TRACKING NO.	PERSON ORDERING OR CONTACT	RECEIVED BY & DATE
7/16/01	Fedex	Kansas Dept of Agriculture	792426544072	S. Tomasino	Steve Tomasino
7/16/01	Fedex	Kansas Dept of Agriculture	791612225919	S. Tomasino	Steve Tomasino
7/16/01	Fedex	Bayer	453662073120	J. Thompson	X
7/16/01	Fedex	ASRC	791612115823	M. Moody	
7/16/01	Fedex	Origin ID	482735770456	D. Slizys	
7/16/01	Fedex	Comp. Sci. Corp	491611131102	D. Bradley	MP Bradley
7/16/01	Fedex	Satistical Des.	828011382673	W. Davis	
7/16/01	Fedex	lockheed	791612294929	S. Roberson	
7/16/01	Fedex	CSC	479515802856	S. Orchena	
7/16/01	Fedex	EPA	823548660390	M. E. Schultz	
7/16/01	Fedex	EPA	823548641166	C. Caporale	
7/16/01	UPS	GSA	1Z5270X0309060828	M. Price	MP
7/16	UPS	Ce.MC	1Z012275014420558 6	D. Slizy	
7/16	UPS	Horizon Tech.	1Z030E840351096321	A. Turner	SCW
7/16	UPS	Agilent Tech	1ZE0675030136 1307	S. Vaquer	SCW
7/16/01	UPS	Fisher	1Z199925034492329 5	Joe / Betty	X
7/16/01	UPS	Dell	1ZV54 R6E 420324 0145	R. Dreisch	
7/13/01	Fedex Ground	Sigma	9611019	D. Wright	X
7/16/01	Lee	Capitol Tech.	787904	W. Mills	
7/12/01	Airco	Airco	259648-1 5 Boxes	W. Mills	
7/16/01	Pitt Ohio	Fisher	16202810 2 Boxes	J. Ullrich	X
7/16	UPS	LAB SAFETY	1Z5 85188 03 1491 4071 5 Boxes	T. Cole	X
7/16	Fedex Ground	GSA	914773216	M. Price	MP

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