

10-29-84

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 09-20-84 OUT 10-25-84

Dennis G. Guse *10/29/84*

Reviewed By Dennis G. Guse Date 10-25-84

EPA Reg. No. or File Symbol 4313-51

EPA Petition or EUP No. None

Date Division Received 09-11-84

Type Product Hospital Disinfectant

Data Accession No(s) 254700

Product Manager 32 (Castillo)

Product Name Super Oxide

Company Name Carroll Company

Submission Purpose Amendment (revised use-dilution) with
efficacy data and labeling

Type Formulation Liquid concentrate

<u>Active Ingredient(s):</u>	<u>%</u>
Isopropanol	13.50
Potassium o-benzyl-p-chlorophenate	10.10
Potassium o-phenylphenate	4.90
Potassium p-tertiary-amylphenate	2.50
Tetrasodium ethylenediaminetetraacetate	0.39

200.0 Introduction

200.1 Uses

"One-step" cleaner-disinfectant, fungicide (pathogenic fungi), and tuberculocide for floors, walls, woodwork, and equipment in hospitals, clinics, veterinary hospitals, rest homes, athletic departments, and industrial plants.

The current amendment is intended to support a revision in the recommended use dilution from 1 oz/gal to ½ oz/gal.

200.2 Background

An amendment for the same purpose was received 07-24-79 and found to be deficient in a review by TSS (Efficacy), DB, RD, dated 02-07-80. The deficiencies were transmitted to the registrant with Mr. Castillo's letter dated 03-07-80. The deficiencies were not corrected.

The current amendment appears to contain much of the same data with the same deficiencies, although some additional data appears to have been included. The labeling deficiencies also appear uncorrected.

201.0 Data Summary

201.1 Brief Description of Tests

- a. Reports on germicidal, fungicidal, and tuberculocidal efficacy by Ronald D. Creamer, Microbiologist, Carroll Company, Garland, TX 75041, dated from 03-01-77 to 03-07-79 (Accession No. 254700).
- b. Report for AOAC confirmative tuberculocidal tests by Barbara B. Colina and Gayle K. Mulberry, Microbiological Services Division, Hill Top Research, Inc., Miamiville, OH 45147, dated from 09-20-82 to 12-20-82 (Accession No. 254700).

201.2 Test Summaries

a. AOAC Use-Dilution Method

1. Modifications: None reported.
2. Samples: Super Ocide, Lots No. 75302, 75303, and 75304. Preparation dates and test dates are provided under Results.
3. Dilution: 1/256.
4. Exposure: 10 minutes at 20C (per method).

5. Test Organisms: Staphylococcus aureus (phenol resistance less than 1:60 to 1:65), Salmonella choleraesuis (phenol resistance less than 1:90 to 1:95), and Pseudomonas aeruginosa (phenol resistance 1:80 to 1:85).
6. Subculture Media/Neutralizer: Not reported.
7. Incubation: 48 hours at 37C (per method).
8. Results:

Lot No.	No. Positive/Total Carriers		
	<u>Staphylococcus aureus</u>	<u>Salmonella choleraesuis</u>	<u>Pseudomonas aeruginosa</u>
75302 (02-14-77)*	0/30 (03-05-77)**	0/30 (03-19-77)	0/30 (03-01-77)
	0/30 (03-07-79)	0/30 (03-27-77)	
75303 (06-01-77)	0/30 (06-19-77)	0/30 (08-18-77)	0/30 (06-17-77)
	0/30 (06-27-77)	0/30 (09-15-77)	
75304 (10-25-77)	0/30 (01-15-78)	0/30 (02-22-78)	0/30 (11-12-77)
	0/30 (02-02-78)	0/30 (03-12-78)	
	0/30 (11-18-78)		
	0/30 (11-30-78)		

* Preparation date ** Testing date

9. Conclusions: No failures reported vs. the three test bacteria at the revised use-dilution of 1/256. However, the number of carriers employed with Pseudomonas aeruginosa were insufficient. In addition, the subculture medium and procedure employed to insure neutralization were not reported.

It should be noted that the 60-day shelf-life stability requirement has already been satisfied by previously submitted data. Refer to the previous review by TSS (Efficacy), DB, RD, dated 02-07-80, in this regard.

b. AOAC Fungicidal Test

1. Modifications: None reported.

2. Samples: Super Ocide, Lots 75303 (prepared 06-01-77) and 75304 (prepared 10-25-77).
3. Dilution: 1/100 to 1/300. The results at 1/225 to 1/300 only are summarized.
4. Exposure: 5, 10, and 15 minutes at 20C (per method).
5. Test Organism: Trichpohyton mentagrophytes (var. interdigitale), phenol resistance 1:65.
6. Subculture Media/Neutralizer: Glucose broth for subcultures and resubcultures.
7. Incubation: 10 days at 25-30C (per method).
8. Results:

Lot No.	Dilution	Growth (+) or No Growth (0) After					
		5 min.		10 min.		15 min.	
		S	RS	S	RS	S	RS
75303	1/225	+	0	0	0	0	0
	1/256	+	0	0	0	0	0
	1/300	+	+	+	0	+	0
75304	1/225	+	0	0	0	0	0
	1/256	+	+	0	0	0	0
	1/300	+	+	+	+	0	+

S = Subculture RS = Resubculture

9. Conclusions: No growth after 10 minutes at dilutions of 1/225 or 1/256; growth reported after 10 minutes at dilution of 1/300.
- c. AOAC Confirmative Tuberculocidal Activity Test (Carroll Company)
1. Modifications: None reported.
 2. Sample(s): Super Ocide, Lot 75303 (prepared 06-01-77).
 3. Dilution: 1/256.
 4. Exposure: 10 minutes at 20C (per method).
 5. Test Organism: Mycobacterium tuberculosis var. bovis (BCG), phenol resistance 1:75 (no growth at 1:50; growth at 1:75).
 6. Subculture Media/Neutralizer: Modified Proskauer-Beck medium (#1), Middlebrook 7H9 broth - Difco B (#2), and Kirchner's medium - Difco (#3).

7. Incubation: 90 days at 37C (per method).

8. Results:

<u>Subculture Medium</u>	<u>No. Positive/Total Carriers</u>
#1	0/10
#2	0/10
#3	0/10

9. Conclusions: No failures reported at the revised use-dilution of 1/256.

d. AOAC Confirmative Tuberculocidal Activity Test (Hill Top Research)

1. Modifications: The following modifications were incorporated in the method to adapt the procedure to the laboratory facilities:

- i. The culture of test organisms used as inoculum was not shaken during the 21-25 days incubation period;
- ii. Glass culture tubes were of a smaller size than specified in the method. The volume of media added to those smaller tubes was also reduced. The smaller size was selected based on availability of disposable glassware. Disposable glassware is used to avoid potential problems with residue accumulation in the glassware.

2. Sample(s): Super Ocide, Lot 75304 (prepared 10-25-77).

3. Dilution: 1/256.

4. Exposure: 10 minutes at 20C.

5. Test Organism: Mycobacterium tuberculosis var. bovis (BCG), phenol resistance 1:75 (no growth at 1:50; growth at 1:75).

6. Subculture Media/Neutralizer: Modified Proskauer-Beck (#1), Middlebrook 7H9 broth (#2), and Kirchner's medium - Difco (#3).

7. Incubation: 90 days at 37C.

8. Results:

<u>Subculture Medium</u>	<u>No. Positive/Total Carriers</u>
#1	0/10
#2	0/10
#3	0/10

9. Conclusions: No failures reported at the revised use-dilution of 1/256.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 4313-51

Date Division Received 09-11-84

Data Accession No(s). 254700

Product Manager No. 32 (Castillo)

Product Name Super Ocide

Company Name Carroll Company

202.0 Recommendations

202.1 Efficacy Supported by the Data

- a. The submitted data are adequate to support effectiveness of the product as a general disinfectant vs. Staphylococcus aureus and Salmonella choleraesuis at a use-dilution of $\frac{1}{2}$ ounce per gallon of water (1/256) on pre-cleaned, hard, non-porous surfaces that are thoroughly wet by the solution for at least 10 minutes.

However, essential procedural information identifying the subculture medium and neutralization procedures employed in the tests was not included in the submitted data reports for the AOAC Use-Dilution Method testing. This information must be submitted to validate the data.

- b. The submitted data are adequate to support effectiveness of the product as a fungicide against pathogenic fungi (Trichophyton mentagrophytes) at a use-dilution of $\frac{1}{2}$ ounce per gallon of water (1/256) on pre-cleaned, hard, non-porous surfaces that are thoroughly wet by the solution for at least 10 minutes.
- c. The submitted data are adequate to support effectiveness of the product as tuberculocide (Mycobacterium tuberculosis) at a use-dilution of $\frac{1}{2}$ ounce per gallon of water (1/256) on pre-cleaned, hard, non-porous surfaces that are thoroughly wet by the solution for at least 10 minutes.

202.2 Insufficient Data

The submitted data are insufficient to support effectiveness of the product as a hospital disinfectant vs. Pseudomonas aeruginosa. The submitted data consisted only thirty carriers with each of three samples vs. P. aeruginosa whereas sixty carriers are required with each sample. Therefore, additional data are required to support efficacy of the product as a hospital disinfectant vs. P. aeruginosa.

202.3 Efficacy Not Supported by the Data

None of the submitted data were developed in the presence of organic soil (5% blood serum) to support effectiveness of the product as a "one-step" cleaner-disinfectant. In lieu of this, the directions for use must specify pre-cleaning of surfaces prior to application of the product as a disinfectant. This was pointed out in the review of the previous amendment for this product which accompanied Mr. Castillo's letter of March 7, 1980.

202.4 Additional Data Required to Support Efficacy

As indicated in the previous review for the amendment for this product, the amount of additional data required depends on the use pattern to be supported, i.e., "two-step" (pre-cleaning followed by disinfecting) or "one-step" (cleaning and disinfecting in one operation).

a. "Two-step" cleaning and disinfecting:

In order to complete the requirements to support efficacy of the product as a hospital disinfectant at a use-dilution of 1/256 on pre-cleaned, hard, non-porous surfaces, sixty carriers on each of two samples, representing two different batches, must be tested with Pseudomonas aeruginosa. A third 60-day shelf-life stability sample will not be required.

In addition, to complete the submitted data, the subculture medium and neutralization procedures employed in the submitted AOAC Use-Dilution Method testing must be identified. Refer to the attached DIS/TSS-2 enclosure, item 7. Also, refer to the attached DIS/TSS-3 enclosure for guidance in reporting of data.

b. "One-step" cleaning and disinfecting:

To support efficacy of the product as a hospital disinfectant, fungicide against pathogenic fungi, and tuberculocide at a use-dilution of 1/256 on hard, non-porous surfaces in the presence of moderate amounts of organic soil (5% blood serum), data must be developed and submitted as indicated in the attached DIS/TSS-1 enclosure, item (c), and DIS/TSS-6 enclosure, items (A) and (B), with the reduced batch replication indicated in the DIS/TSS-2 enclosure, item 8. All tests must be modified to include organic soil (5% blood serum) and microorganism survival on control carriers as indicated in the attached DIS/TSS-2 enclosure, items 4 and 6. Also, refer to the attached DIS/TSS-3 enclosure for guidance in reporting of data.

203.0 Labeling

- a. In lieu of data to support efficacy as a "one-step" cleaner-disinfectant in the presence of organic soil, the directions for use must be revised to specify pre-cleaning of surfaces prior to application of the product as a disinfectant, e.g. "Before disinfecting, thoroughly pre-clean surfaces." Delete the phrase "in one operation" from "Where a need exists to clean and disinfect thoroughly in one operation."
- b. The directions for use must be expanded to specify treatment of hard, non-porous surfaces, i.e., ". . . for general hospital use on hard, non-porous surfaces such as floors, walls, woodwork, and equipment . . ."
- c. The isopropanol and tetrasodium ethylenediamine tetraacetate in this product should be considered as inert ingredients in the ingredient statement. Refer to the Federal Register, Vol. 47, No. 126, Wednesday, June 30, 1982, p. 28377.



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

EFFICACY DATA REQUIREMENTS

Disinfectants for Use on Hard Surfaces

- (a) Limited efficacy claims. The label of a disinfectant which is effective against a specific major group of microorganisms only (e.g., Gram-positive or Gram-negative) must specify the major group against which it is effective.
- (1) Test requirements. The AOAC Use-Dilution Method (for water-soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products) is required. Sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against Salmonella choleraesuis ATCC 10708 (for effectiveness against Gram-negative bacteria) or Staphylococcus aureus ATCC 6538 (for effectiveness against Gram-positive bacteria). (Sixty carriers per sample; a total of 180 carriers.)
- (2) Performance requirements. To support products represented in labeling as "disinfectants", killing on 59 out of each set of 60 carriers is required to provide effectiveness at the 95% confidence level.
- (b) General or broad-spectrum efficacy claims. Label claims of effectiveness as a "general disinfectant" or representations that the product is effective against a broad spectrum of microorganisms are acceptable if the product is effective against both Gram-positive and Gram-negative bacteria.
- (1) Test requirements. Use the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test as in (a)(1). Sixty carriers must be tested against each of both S. choleraesuis and S. aureus with each of 3 samples, representing 3 different batches, one of which is at least 60 days old. (120 carriers per sample; a total of 360 carriers.)
- (2) Performance requirements. Same as in (a)(2) above.
- (c) Hospital or medical environment efficacy claims. Label claims for use of disinfectants in hospital or medical environments are acceptable only for those products that are effective for general or broad-spectrum disinfection and additionally against the nosocomial bacterial pathogen Pseudomonas aeruginosa.
- (1) Test requirements. Employ the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test as in (a)(1). Sixty carriers must be tested against each of S. choleraesuis, S. aureus, and Pseudomonas aeruginosa ATCC 15442 with each of 3 samples, representing 3 different batches, one of which is at least 60 days old. (180 carriers per sample; a total of 540 carriers.)

- (2) Performance requirements. Same as in (A)(2) above.
- (d) Other microorganisms. Substantiated label claims of effectiveness of a disinfectant against specific microorganisms other than the designated test microorganism(s) are permitted, but not required, provided that the target pest is likely to be present in or on the recommended use areas an surfaces and thus may present a potential problem.
- (1) Test requirements. Effectiveness of disinfectants against specific microorganisms other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products Test, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method (II. Confirmative In-Vitro Test), but not including viruses, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test as in (a)(1). Ten carriers must be tested against each specific microorganism with each of 2 samples, representing 2 different batches. (10 carriers per sample; a total of 20 carriers.)
- (2) Performance requirements. Killing of the test microorganism on all carriers is required. Plate count data, on appropriate culture media, must be submitted on each test microorganism to disclose that a concentration of at least 10^4 microorganisms survive the carrier-drying step in order to provide meaningful results.



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OFFICE OF TOXIC SUBSTANCES

EFFICACY DATA REQUIREMENTS

Supplemental Recommendations

When an antimicrobial Agent is intended for a use pattern that is not reflected by the test conditions specified in the Recommended Methods, one or more test conditions specified in the method must be modified and/or supplementary data developed in order to provide meaningful results relative to the conditions of use. The following basic information is critical to the development and submission of appropriate data.

1. EXPOSURE PERIOD

All products tested by the recommended methods may be tested at the exposure periods prescribed in those methods. However, if the product is intended for use at exposure periods shorter or longer than those specified in the method, the method must be modified, in a manner acceptable to the Agency, to reflect the deviation in exposure intended. A modification to provide a shorter exposure period is restricted by the manipulative limitations inherent in the method, while a modification to provide a longer exposure period is restricted by the conditions applicable to the use pattern. If a ten-minute exposure period is necessary for the antimicrobial agent to be effective against the test microorganism the product cannot be represented as an "instantly active" product, or cannot be represented as being "effective in 30 seconds," "one minute," or at any time period shorter than 10 minutes. Also, the product cannot be recommended for use in a manner which is inconsistent with the exposure period necessary for effectiveness (as, for example, "Spray on surface, and immediately wipe with clean cloth") unless the standard method has been modified and reflects efficacy under such conditions of use. In any case, the exposure period or manner of use necessary to provide efficacy must be featured prominently on the product label.

2. TYPE OF SURFACE

When an antimicrobial agent is intended to be effective in treating a hard porous surface, some of the Recommended Methods may be modified to simulate this more stringent condition by substitution of a porous surface carrier (such as a porcelain penicylinder or unglazed ceramic tile) for the non-porous surface carrier (stainless steel cylinder or glass slide) specified in the method. In addition, control data, described below in Supplemental Recommendation No. 6, must be developed to assure the validity of the test results when this modification of the method is employed. In no case may a surface carrier which represents a less stringent condition be substituted for a surface carrier which is specified in the Recommended Method.

3. HARD WATER

The Recommended Methods may be modified to demonstrate the effectiveness of an antimicrobial agent in hard water. The hard water tolerance level may differ with level of antimicrobial activity claimed. To establish disinfectant efficacy in hard water, all microorganisms (bacteria, fungi, viruses) claimed to be controlled must be tested by the appropriate Recommended Method at the same hard water tolerance level.

4. ORGANIC SOIL

An antimicrobial agent identified as a "one-step" cleaner-disinfectant, cleaner-sanitizer, or one intended to be effective in the presence of organic soil must be tested for efficacy by the appropriate method(s) which have been modified to include a representative organic soil such as 5% blood serum. A suggested procedure to simulate in-use conditions where the antimicrobial agent is intended to treat dry inanimate surfaces with an organic soil load involves contamination of the appropriate carrier surface with each test microorganism culture containing 5% v/v blood serum (e.g., 19 ml test microorganism culture + 1 ml blood serum) prior to the specified carrier-drying step in the method. Control data, described below in Supplemental Recommendation No. 6, must also be developed to assure the validity of the test results when this modification is incorporated into the method. The organic soil level suggested is considered appropriate for simulating lightly or moderately soiled surface conditions. When the surface to be treated has heavy soil deposits, a cleaning step must be recommended prior to application of the antimicrobial agent. The effectiveness of antimicrobial agents must be demonstrated in the presence of a specific organic soil at an appropriate concentration level when specifically claimed and/or indicated by the pattern of use. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test, involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level (5×10^6 /ml) of conidia.

5. RE-USE

The Recommended Methods are designed to demonstrate efficacy of a freshly prepared antimicrobial solution intended for a single application. When the same use solution is intended for repeated applications, testing must be conducted in accordance with a test protocol specially designed to demonstrate retention of the claimed level(s) of antimicrobial activity in the use solution after repeated microbial and other appropriate challenges (such as supplemental recommendations indicated above) and stress conditions (such as an inadvertent or incidental dilution inherent in the use pattern) over the period of time or number of times specified in the directions for use.

6. MICROORGANISM SURVIVAL AFTER DRYING ON A HARD SURFACE

Quantitative determinations of the viable microbial concentration on the untreated control carrier after drying are required in order to determine the validity of the test results obtained with treated carriers when the Recommended Methods are modified to include such elements as (i) test microorganisms not specified in the method, (ii) substitution of a porous surface (e.g., porcelain penicylinder, unglazed ceramic tile) for the specified nonporous surface (stainless steel cylinder, glass slide), and/or (iii) an organic soil load. The detailed protocol for this testing must include: (i) preparation of inoculum, (ii) application of inoculum to the carrier, (iii) the time/temperature and relative humidity conditions for drying the microorganisms on the carrier, (iv) the technique for removal of the microorganisms from the carrier, and (v) the specific assay procedure indicating such details as replication, subculture media/diluents, and the incubation time/temperature conditions for the enumeration procedure employed. The test results must include the individual counts obtained by the method.

7. NEUTRALIZATION

For each antimicrobial product, procedures must be employed that will preclude residual effects of the active ingredient(s) in the subculture medium. A specific medium capable of neutralizing the antimicrobial effects of a product (whenever one is known) should be employed prior to the microbiological assay. Some of the Recommended Methods rely solely upon the selection of an appropriate subculture medium to neutralize the antimicrobial effects of certain general types of chemical compounds (active ingredients). However, to document absence of residual effects of the active ingredient(s) in the subculture medium, the following testing is necessary: (i) secondary subcultures must be performed to demonstrate that antimicrobial effects were overcome, or (ii) at the conclusion of the incubation period specified or employed in the method, the primary culture medium with test carrier must be inoculated with approximately 10 microorganisms/ml of the specific culture under test (documented by actual plate counts) and reincubated for the specified period to demonstrate that the subculture medium was capable of supporting bacterial growth.

8. BATCH REPLICATION FOR MODIFIED TESTS

Where the required batch replication has already been performed and accepted for a product registration with unmodified tests by the Recommended Methods, additional testing at the same use concentration under modified conditions (e.g., different exposure period, presence of organic soil or hard water, porous surface carrier, etc.) may be conducted with reduced batch replication, as follows: (i) for basic efficacy claims (e.g., sterilizers, disinfectants, or sanitizers), 2 samples, representing 2 different batches, instead of 3, and (ii) for supplemental efficacy claims (e.g., fungicides, virucides, or tuberculocides), one sample instead of 2.



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EFFICACY DATA REQUIREMENTS

Reporting of Data

Systematic and complete descriptions of the tests employed and the results obtained are essential for proper review and evaluation of product performance by the Agency. All test reports must include identification of the testing laboratory or organization, when and where the tests were conducted, and the name of the person(s) responsible for the conduct of the tests.

- (1) Recommended Methods. When the Recommended Methods (such as standard AOAC tests) are employed to develop efficacy data, certain minimal information must be provided in the test report. The report must include, but is not limited to, the following:
 - (a) Test employed, and any modifications thereto;
 - (b) Test microorganisms employed, including identification of the specific strain (ATCC or other);
 - (c) Concentration or dilution of product tested and how prepared;
 - (d) Number of samples, batches, and replicates tested;
 - (e) Preparation date of each product batch (individually formulated preparation of the product);
 - (f) Phenol resistance of test microorganisms (actual test results);
 - (g) Identification of all material or procedural options employed, where such choice is permitted or recommended in the test method selected (for example, growth media, drying time for inoculated carriers, neutralizer and/or subculture media, secondary subculturing);
 - (h) Complete report of results obtained for each individual replication;
 - (i) Any control data essential to establish the validity of the test.
- (2) Modification of Recommended Methods. Where Recommended Methods are significantly modified to support specific claims and/or use patterns for a product, the protocol employed for modifying the test must be provided in specific detail with the test report. The applicant may submit the proposed modification for review and evaluation prior to initiation of the test.
- (3) Other Methods. When Recommended Methods, or modification thereto, are not employed to develop efficacy data (such as actual in-use or many kinds of simulated-use testing), complete testing protocols must be submitted with the test reports. All materials and procedures employed in testing must be described in a manner consistent with original research reports published in technical or scientific journals. Where references to published reports or papers are made, copies or reprints of such references should be provided with the test reports. Proposed testing protocols for in-use or simulated-use studies of this kind may be submitted for review and evaluation by the Agency prior to initiation of the tests.

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

EFFICACY DATA REQUIREMENTS

Supplemental Efficacy

- (A) Pathogenic fungi. (1) Test requirements. Effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data derived from each of 2 samples representing 2 different batches using the AOAC Fungicidal Test.
- (2) Performance standard. The highest dilution that kills all fungal spores is the minimum effective concentration.
- (3) Alternative test requirements. Alternatively, the AOAC Use Dilution Method, modified to conform with appropriate elements in the AOAC Fungicidal Test, may be employed. If the product is intended for use as a spray, the AOAC Germicidal Spray Products Test must be employed. The inoculum in the above tests must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 samples representing 2 different batches must be employed in the test.
- (4) Alternative performance standard. Killing of the test microorganism on all carriers is required.
- (5) Permitted labeling claims. Acceptability of claims against pathogenic fungi on environmental surfaces is contingent upon correlation between the claim and the recommended use areas and surfaces to be treated where pathogenic fungi are likely to be a problem.
- (B) Mycobacterium tuberculosis. (1) Test requirements. Effectiveness against M. tuberculosis must be substantiated with data derived on 10 carriers by the AOAC Tuberculocidal Activity Method (II Confirmative In Vitro Test for Determining Tuberculocidal Activity) for each of 2 samples representing 2 different batches of a liquid product under test. If the product is a spray, the procedure must be modified to conform with the AOAC Germicidal Spray Products Test using the media, microorganisms, and other elements described in the AOAC Tuberculocidal Activity Method.
- (2) Performance standard. Killing of the test microorganism on all carriers, and no growth in any of the inoculated tubes of two additional media, is required.

- (3) Permitted labeling claims. Labels of products claiming disinfection of inhalation therapy and/or pulmonary diagnostic equipment, or unidentified medical equipment and/or instruments, or all-inclusive hard non-porous surfaces in the medical environment but which have not been tested for effectiveness against Mycobacterium tuberculosis must bear the following statement: "This product has not been tested for effectiveness against Mycobacterium tuberculosis, and must not be relied upon when a tuberculocidal product is desired." In lieu of this statement, the label recommendations must clearly exclude the use of the product on inhalation therapy and/or pulmonary diagnostic equipment.
- (C) Phenol coefficient (s). (1) Test requirements. Phenol coefficients for Salmonella typhi (the only official test organism), and for any additional Gram-negative or Gram-positive asporogenous bacteria must be determined by the AOAC Phenol Coefficient Method on each of 2 samples representing 2 different batches against each bacterium.
- (2) Performance standard. The Phenol Coefficient is a numerical value that compares the bactericidal concentration of a disinfectant to the bactericidal concentration of pure phenol. This numerical value is obtained by dividing the greatest dilution of disinfectant killing S. typhi in 10 minutes, but not in 5 minutes, by the greatest dilution of phenol showing the same results.
- (3) Permitted labeling claims. (a) Phenol coefficient claims are permitted only on labels of those products when the value claimed can be considered meaningful and not misleading. Only when the phenol coefficient of a product, as claimed on the label, can be multiplied by the factor "20" to provide the effective use dilution of the product (as confirmed by the AOAC Use Dilution Method) will the phenol coefficient claim be permitted on the label.
- (b) "Phenol Coefficient" tables which list phenol coefficient values for numerous bacteria are frequently included in collateral labeling, such as technical bulletins or brochures for formulated products, technical grade chemicals, and chemicals for manufacturing-use products only. These claims ("Phenol Coefficient" tables) must be prominently prefaced with a statement such as: "The following Phenol Coefficients are intended only to indicate the broad-spectrum activity of the product. This information must not be interpreted as having any relevance to the use patterns recommended, effective dosages, or activity against specific microorganisms when used as directed."