2-7-80

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 8-10-79 OUT 2-7-80

Reviewed by Dorothy M Portner Date 2-7-80

EPA Reg. No. or File Symbol 4313-51

EPA Petition or EUP No.

Date Division Received 7-24-79

Type Product(s): I, (D), H, F, N, R, S Hospital Disinfectant

Data Accession No(s). 238851

Product Mgr. No. 32

Product Name(s) Super Ocide

Company Name(s) Carroll Company

Submission Purpose Amended Application to decrease the use dilution.

Chemical & Formulation Liquid Concentrate to be diluted

Active Ingredient(s):	%
Isopropanol	13.50
Potassium ortho-benzyl-para-chlorophenate	10.10
Potassium ortho-phenylphenate	4.90
Potassium para-tertiary-amylphenate	2.50
Tetrasodium ethylene-diamine tetraacetate	0.39

200.0 Introduction

200.1 Uses

One-step cleaner-disinfectant for floors, walls, woodwork and equipment in hospitals, clinics, veterinary hospitals, rest homes, athletic departments, industrial plants.

200.2 Background Information

This submission, received 7-24-79, is an amended application to change the use dilution from 1 oz./gal. to 1/2 oz./gal. This review addresses only this amendment.

200.2.1 Factors Affecting the Amount/Type of Data Required

Factors affecting the amount/type of data required involve: carrier replication, sample replication and shelf-life stability replication. All basic data to substantiate a disinfectant must be developed with 60 carriers to provide effectiveness at the 95% confidence level. In this instance, this requirement could be fulfilled by testing an additional 30 carriers with each test microorganism and batch sample, but the results would not be meaningful since these batch samples are now about 3 years old. The original data supporting this registration demonstrate the effectiveness of a replicate sample at the use dilution of 1:128. Thus only one sample would be required to demonstrate efficacy at the original use dilution (1:128) for additional supplemental claims and/or test conditions as indicated in (8) of the DIS/TSS-2 enclosure. However, in this instance, efficacy is claimed for a higher dilution of the product (1:256). Thus, replicate samples will be required to support the complete data base developed for this new use dilution. Only the third batch sample (the shelf-life stability replication for an aged batch) will be omitted from the data requirements imposed on the new use dilution since both the original data and the submitted data would substantiate efficacy of an aged batch sample.

201.0 Data Summary

The submitted data, developed by the Carroll Company, are summarized below.

AOAC Use Dilution Method

Lot No.	No. Positive/Total Carriers S. aureus[1]	S. choleraesuis[2]	P. aeruginosa[3]
75302 (2-14-77)*	0/30 (3-7-79)**	0/30 (3-27-77)	0/30 (3-1-77)
75303 (6-1-77)	0/30 (6-19-77)	0/30 (9-15-77)	0/30 (6-17-77)
75304 (10-25-77)	0/30 (11-30-78)	0/30 (2-22-78)	0/30 (11-12-77)

1. Phenol Resistance = 1:60
2. Phenol Resistance = 1:90
3. Phenol Resistance = 1:80

*Date of product batch preparation
** Date of product batch testing
Use Dilution = 1:256
Subculture medium - not identified
Neutralization procedure - not indicated

AOAC Tuberculocidal Activity Test

Culture Medium	No. Positive/Total Carriers*
Modified Proskauer - Beck	0/10
Middlebrook 7H9	0/10
Kirchner	0/10

Phenol Resistance Dilution	No. Positive/Total Carriers**
1:50	0/10
1:75	8/10

*Use Dilution = 1:256
**Primary culture medium not identified; secondary subculture results not indicated.

AOAC Fungicidal Test

Lot no.*	Dilution	5 min.	10 min.	15 min.
75303	1:225	+	-	-
	1:256	+	-	-
	1:300	+	+	+
75304	1:225	+	-	-
	1:256	+	-	-
	1:300	+	+	-

*For each lot, 2 subsamples/dilution tested
Subculture medium = Glucose broth; neutralizer incorporated into the medium not indicated.

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TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 4313-51

Date Division Received 7-24-79

Product Manager No. 32

Product Name Super Ocide

Company Name Carroll Company

202.0 Recommendations

202.1 Efficacy Claims Supproted By the Data

The fungicidal data submitted support efficacy of the product against pathogenic fungi (specifically against Trichophyton mentagrophytes) at a use dilution of 1/2 ounce per gallon of water (1:256) for pre-cleaned, hard, non-porous surfaces that are thoroughly wetted by the use solution for at least 10 minutes.

However, to complete the data report, the procedures employed to eliminate residual effects of the active ingredients in the subculture medium must be submitted.

202.2 Insufficient Data/Information

The required basic data, developed with 30 carriers for Staphylococcus aureus, Salmonella choleraesuis and Pseudomonas aeruginosa on each of 3 samples by the AOAC Use Dilution Method, are not sufficient to meet current data requirements indicated in (B)(3) of the DIS/TSS-1 enclosure. Moreover, essential procedural information, such as the subculture medium and neutralization procedures employed in testing, was not indicated in the submitted data report.

The tuberculocidal data, developed for only one sample, also do not meet current data requirements for supplemental efficacy indicated in the DIS/TSS-6 enclosure. Moreover, the Phenol Resistance data must be clarified in order to validate the test data. The test results for each of three culture medium employed in the tests with phenol must be submitted. The data report provides results for only one unidentified culture medium.

202.3 Efficacy Claims Not Supported By The Data

None of the submitted data were developed in the presence of organic soil to support the product as a one-step cleaner-disinfectant.

202.4 Additional Data Required to Support Efficacy Claims

The amount of additional data required depends upon the use pattern to be reflected by the supporting data.

A. Two-step Cleaner-Disinfectant

The basic data required to substantiate the efficacy of the product for disinfecting pre-cleaned hard surfaces at the proposed recommended use dilution of 1:256 must be developed with sufficient carrier replication to provide effectiveness at the 95% confidence level. Thus, 60 carriers on each of 2 samples, representing different batches, must be tested against each of the following: S. aureus, S. choleraesuis, and P. aeruginosa. The submitted data, when clarified, will be sufficient to substantiate efficacy of an aged product batch and to satisfy the shelf-life stability requirement.

Data, developed for an additional batch sample, will be required to support the tuberculocidal claim.

B. One-step Cleaner-Disinfectant

To substantiate product efficacy for cleaning and disinfecting lightly or moderately soiled hard surfaces in a one-step operation at the proposed recommended use dilution of 1:256,the data, indicated in (B)(3) of the DIS/TSS-1 enclosure, must be developed in the presence of organic soil by a modified AOAC Use Dilution Method. However, data for only 2 batch samples will be required since previously developed data will fulfill the shelf-life stability testing required for an aged batch sample.

To support fungicidal and tuberculocidal efficacy claims for the product used as a one-step cleaner-disinfectant, the data, indicated in (A)(1) or (3) and (B) of the DIS/TSS-6 enclosure, must also be developed in the presence of organic soil.

The DIS/TSS-2 enclosure provides basic information critical to the development of modified AOAC methods to test product efficacy in the presence of organic soil. The DIS/TSS-3 enclosure indicates the detailed information that must be included in the data report(s) submitted.

202.5 Use Limitations

Label directions reflecting a two-step cleaner-disinfectant use pattern must include instructions for cleaning the surface prior to application of the use solution to the clean surfaces for disinfection.

Label directions reflecting a one-step cleaner-disinfectant use pattern must include instructions for the removal of gross filth or heavy soil deposits from the surfaces prior to application of the use solution to lightly or moderately soiled surfaces for disinfection.

Information to be included in the label directions is indicated in the DIS/TSS-15 enclosure.