

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW-I

Antimicrobial Program Branch

IN 09-04-91

OUT 01-03-92

Reviewed by Lisa A. Andersen Date 01-03-92

EPA Reg. No. or File Symbol 065402-R

EPA Petition or EUP No. None

Date Division Received 11-05-91

Type Product(s) A Liquid Sanitizer

MRID No.(s) 420229-02

Product Manager No. PM 31 (Lee)

Product Name(s) Vigorox Liquid Sanitizer

Company Name(s) Peroxygen Chemicals Division

Submission Purpose An Application for Me-too product registration

Type Formulation Liquid product used diluted.

Active Ingredient(s) 3

Peroxyacetic Acid..... 5.0
Hydrogen Peroxide..... 20.0

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202.0 Recommendations

These data are not acceptable. There is information lacking from the study which is necessary for the review. The phenol resistance of the test organisms is not given. The hardness of the water used to dilute the product sample is not given and the prepared hard water must be checked chemically for hardness at the time testing is done. Also, need to describe how the dilutions of the test samples were prepared, the volume of test product added to a specific volume of hard water. Refer to DIS/TSS-3.

Incorrect neutralizer and neutralization procedure was employed. This cannot be repaired in this report and therefore the test must be repeated before registration may be granted.

Failed to conduct inspection during the course of the study. This is a lack of GLP compliance. Refer to 40 CFR, Part 160.35.

Need to list complete results for each replication.

203.1 Labelling

According to 21 CFR 178.1010 (b) (25), your sanitizing solution may be used on food-processing equipment, ~~and~~ and utensils, ~~and food-contact surfaces in public places.~~ To use on other food-contact articles such as wooden utensils, chopping blocks, dairy processing equipments, beverage containers, milk containers, milk cans, and milk processing equipments, you must submit a letter from the Food and Drug Administration. For further information, contact:

Gillian Robert-Baldo
Indirect Additives Branch, HFF-335
Division of Food and Color Additives
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204
Telephone: (202) 472-5690

Under the Hazard Statement, there is a typographical error; the sentence reads, "Do not enter enclosed area is strong..." and should read, "Do not enter enclosed area if strong...".