

9-17-93

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 1

Date RD Received: 07/20/93 Review Start Date: 09-17-93

Date EPA Received: 06/23/93

Project Return Date: 12-30-93 Review Completion Date: 09-17-93

Reviewed by: Arnold E. Layne, Microbiologist Date: 09-17-93

EPA Reg. No. or File Symbol: 49403-23

EPA Petition or EUP No.: NONE

Product Type: Hospital Disinfectant

MRID No(s): 428209-01

Product Manager & Team No.: Douglas PM-32

Product Name: Ocide Hospital Cleaner Disinfectant

Company Name: NIPA Laboratories, Inc.

Submission Purpose: Add HIV claim to label.

Product Formulation: Liquid Concentrate

<u>ACTIVE INGREDIENT(S)</u>	<u>%</u>
Ortho-Benzyl-Para-Chlorophenate.....	10.10%
Ortho-Phenylphenate.....	4.90%
Para-Tertiary-Amylphenate.....	2.50%

200.0 INTRODUCTION

200.1 USE(S): Refer to attached label for uses.

200.2 BACKGROUND INFORMATION: The submission, received by RD on 07/20/93, is an amendment to add a HIV-1 claim. Efficacy data was submitted with this application.

201.0 DATA SUMMARY:

MRID # 428209-1

The study titled "Virucidal Efficacy of NIPA Laboratories, Inc.'s Super Ocide Hospital Cleaner-Disinfectant Against the Human Immunodeficiency Virus" was performed by Bonnie J. Bowdon, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35255-5305.

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

ANTIMICROBIAL PROGRAM BRANCH

EFFICACY REVIEW - FORM 2

EPA Registration No.: 49403-23Date EPA Received: 06/23/93Date RD Received: 07/20/93Project Return Date: 12/30/93Review Start Date: 09/17/93Review Completion Date: 09/17/93MRID No(s): 428209-01Product Manager & Team No.: Douglas PM-32Product Name: Ocide Hospital Cleaner DisinfectantCompany Name: NIPA Laboratories, Inc.

202.0 RECOMMENDATIONS

202.1 EFFICACY SUPPORTED BY THE DATA

The submitted efficacy data supports the effectiveness of the product as an effective virucide against the HIV-1 virus when used at a 1:128 dilution in the presence of 380.1 ppm hard water (CaCo3) for a contact time of 10 minutes at room temperature (20-25°C) on hard, inanimate non-porous surfaces.

203.0 LABELING

Add the word "Virucidal*" on the front panel of the label. In addition, place an asterisk (*) beside HIV-1 in the "Directions For Use Against *HIV-1 (AIDS Virus)".