

US EPA ARCHIVE DOCUMENT

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL PROGRAM BRANCH

IN 03/13/97 OUT 03/20/97

Reviewed by Srinivas Gowda Date 03/20/97

EPA Reg. No. or File Symbol 10492-4

LAN Code 10492-4, 497 *Michael E. Johnson*

EPA Petition or EUP No. None

Date Division Received 02-06-97

Type Product Hospital Disinfectant

MRID No (s) None

Product Manager PM 31 (MJohnson)

Product Name DisCide Disinfecting Towelette

PM Team Reviewer None

Company Name Palmero Health Care (PHC)

Submission Review and Evaluation of Proposed Test Protocol For
Evaluating Pre-Saturated Towelettes for Hard Surface
Disinfection against Mycobacterium bovis - Single Use

Type Formulation Single Use Disposable Towelette Saturated with
ready-to-use liquid

Active Ingredient (s): %

n-alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl
benzyl ammonium chloride.....0.12

n-alkyl (68% C12, 32% C14) dimethyl
benzyl ammonium chloride.....0.12

Isopropyl alcohol.....63.0

67104

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2

202.0

Recommendations

202.1

Evaluation of Proposed Modifications to Previously Accepted Pre-Saturated Towelette Protocol for Hard Surface Disinfection Against Mycobacterium bovis BCG

Proposed modifications:

1. Drop 5% blood serum as organic soil from the protocol because DisCide is recommended for use on precleaned surfaces only.

2. An alternate approach for using blood serum with two-step products (For discussion purposes only).

3. Protocol should include the statement "Any airflow that could accelerate evaporation of the product must be prevented from the time the towelette is removed from its container until exposure ends with neutralization of the disinfectant. For example, if a vented hood is used, it must be turned off during this period."

202.2

General Comments

The proposed modifications (1 and 3) in your letter of February 6, 1997, to the previously accepted towelette protocol dated 07-26-96, for efficacy testing of DisCide Disinfecting Towelette, EPA Reg. No. 10492-4, are acceptable in meeting the criteria specified in the EPA product performance guidelines for the determination of the tuberculocidal activity of pre-saturated towelettes against Mycobacterium bovis BCG on precleaned, inanimate, hard, non-porous surfaces.

Please note that, the proposed modification number 2 was for discussion purposes only and therefore, it was not accepted. If you have further questions concerning the protocol, please do not hesitate to contact Srinivas Gowda at (703) 308-6354.