

EFFICACY EVALUATION-TEAM 2
RISK ASSESSMENT & SCIENCE SUPPORT BRANCH
ANTIMICROBIAL DIVISION

Date In: 11-14-97 Date Out 01-14-98

EPA Received Date: 09-29-97

RASSB Received Data: 11-17-97

Reviewed by: Bruce H. Mann Microbiologist

Lan Code: 10492-4.298 Michael E. Byrnes

EPA Reg. No. or File Symbol 10492-4

Product Name Isotex 70 Disinfecting Towelettes

Product Type Hospital Disinfectant

Company Name Palmero Health Care (PHC)

MRID No (s): 443903-01

Product Manager/Reviewer & Team No.: Swindell/Terry

Submission Purpose: An amendment to add a claim for Escherichia coli.

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

ACTIVE INGREDIENT (S)	%
n-alkyl (60%, C14; 30%, C16; 5% C12, 5%, C18) dimethyl ammonium chloride	0.12
n-alkyl (68% C12, 32% C14) dimethyl benzyl ammonium chloride.....	0.12
Isopropyl alcohol.....	63.00

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200.0 Introduction

200.1 Use (s)

Refer to the attached labeling and the last accepted label dated 05-12-97.

200.2 Background Information

The current product is registered as a pre-saturated hospital disinfectant for hard surfaces. Also, it is listed as being tuberculocidal, virucidal, fungicidal, herpecidal, and bactericidal

The current submission is an amendent to add a label claim against Escherichia coli.

201.0 DATA SUMMARY

201.1 BRIEF DESCRIPTION OF TESTS

Efficacy Data submitted by Palmer Health Care was generated by VioMed Laboratories, Inc., Minneapolis, MN 55343. The submitted data were developed by the Official Methods of the AOAC, 15th, edition 1990, Germicidal Spray Products as Disinfectant, and following the data requirements indicated in DIS/TSS-1 and-2 enclosures.

201.3 Test Summaries

The reported data developed by the use of a pre-saturated towelettes impregnated with the disinfectant show satisfactory performance.

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