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

Date In: 10-17-97 Date Out 11-17-97

EPA Received Date: 10-03-97

RASSB Received Data: 10-17-97

Reviewed by: Bruce H. Mann Microbiologist

LAN Code: 10492-4.127 *Mehle E. Freund*

EPA Reg. No. or File Symbol 10492-4

Product Name Isotex 70 Disinfecting Towelettes

Product Type Hospital Disinfectant

Company Name Palmero Health Care

MRID No (s): 440006-07 and 440006-08

PM/Reviewer & Team No.: PM-33 Swindell/Terry

Submission Purpose: To review efficacy and to see if efficacy data are supportive of a 1 minute contact time for disinfection.

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 benzyl ammonium chloride	0.12
n-alkyl (68% C12, 32% C14)	
dimethyl benzyl ammonium chloide	0.12
Isopropyl alcohol	63.00

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200.0 Introduction.

200.1 Use (s)

Refer to the proposed attached labeling pinpunched 06-20-97 and the last accepted label dated 05-12-97.

200.2 Background Information.

The product "Isotex 70 Disinfecting Towelettes" is a pre-saturated single use towelette which is recommended for hard, nonporous precleaned surfaces in health care settings such as hospitals, clinics, nursing homes, intensive care units, dental suites and emergency medical settings.

The current submission received 10-17-97 is an amendment to see if basic efficacy data are supportive of a 1 minute contact time for disinfection which were generated against the agency three (3) required test microorganisms for hospital usage and fungicidal data in support of pathogenic fungi claim.

201.0 DATA SUMMARY.

201.1 BRIEF DESCRIPTION OF TESTS.

- A. Data to Support Germicidal Claims of Isotex 70 Towelettes. Report by Norman Miner, Microchem Laboratory, 7423 Airport Freeway, Fort Worth, TX 76118, dated 03-08-96. (MRID #440006-07).
- B. Data to Support Fungicidal Claims of Isotex 70 Towelettes. Report by Norman Miner, Microchem Laboratory, 7423 Airport Freeway, Fort Worth, TX 76118. (MRID #440006-08).

201.2 Test Summaries:

- I. Data for Three (3) Required Test Organisms:
 - A. Method: Simulated-use test modified from the AOAC Germicidal Spray Products Test for a single-use disinfectant-saturated towelette.
 - B. Modifications: For carriers, the inoculum added to one square inch of the non-frosted end of a 25 x 75 mm glass microscopic slide.

For inoculum, a 4.0 mm diameter sterile nichrome wire loop was used to spread over one square inch of the non-frosted end of the slide and allowed to dry for 30-40 minutes at 37 degree centigrade.

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Each of 3 batches of Isotex 70 towelettes was used to wipe the surfaces of 60 slides for each test organism. Hence, each batch was used to wipe 60 sq. in. of glass (equivalent to 60 1-in. x 1-in. slides) for each test organism.

Refer to attachment #1 for additional specifics on "controls", "materials", "methods", and "procedures".

- C. Samples: Isotex 70 towelettes, Batch #HO75-B (no date), Batch #H235-A (no date), and Batch F014-A (06-94, 60 day).
The preparation date of the three (3) test lots must be provided.
- D. Undiluted (single use disposable towelette saturated with ready-to-use solution).
- E. Exposure: 1.0 minute at 22°C.
- F. Subculture medium: Nutrient Broth
Neutralizing growth medium: Dey/Engley neutralizing medium.
- G. Incubation: 48 hours at 35°C.
- H. Test Organisms: Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa.
For phenol resistance, refer to attachment #1.
- I. Results, refer to attachment #2.
- J. Conclusions: Satisfactory performance vs. all test microorganisms for glass plates for a 1 minute exposure time for the slides.

201.2 Test Summaries:

II. Data for Trichophyton mentagrophytes

- A. Method: AOAC Germicidal Spray Products and modified for disinfectant-saturated single-use towelettes for use against pathogenic fungi.
- B. Refer to attachment #3 for "procedures", "simulated methodology", "subculture media", "neutralization", "exposure time", "phenol resistance", "results" and "controls".
- C. Conclusions: Satisfactory performance for lot # H235-A on the first test, and satisfactory performance for lot #HO75-B for a repeat test, however, the first study for lot #HO75-B showed one (1) failure for a 1 minute exposure time under the test conditions.