

11-10-97

An exposure time of 1 minute appears to show a borderline effectiveness for lot #H075-B.

Documentation provided for the slides used in the data reports appear to be satisfactory.

EFFICACY EVALUATION - TEAM 2

RISK ASSESSMENT & SCIENCE SUPPORT BRANCH

ANTIMICROBIALS DIVISION

10492-4

EPA Registration NO.: 10492-43

Date EPA Received 10-03-97

Date RASSB Received: 10-17-97

Project Return Date: 04-31-97

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

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

Product Name: Isotex 70 Disinfecting Towelettes

Company Name: Palmero Health Care

6/9/97

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- 202.0 Recommendations
- 202.0 Claims Related to Human Health
- 202.1 Efficacy Supported by the Submitted Data

- A. The submitted data developed by a simulated-use test modification of the AOAC Germicidal Spray Products Method (i.e., glass plates wiped with towelettes) plates were subcultured) appear adequate to support effectiveness of the product as a disinfectant for hospital or medical areas (vs. *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa* on precleaned, hard, non-porous inanimate surfaces when thoroughly wipe by a saturated towelette and allowed to remain wet for a 1 minute exposure time.

The acceptance is pending the submission of additional information/data which are specified below to 202.3

- B. The submitted fungicidal data developed by a simulated-use test modification of the AOAC Germicidal Spray Products Methods (i.e., glass plates wiped with towelettes) plates were subcultured) appear to show adequate performance of the product as a fungicide against *Trichophyton mentagrophytes* on previously cleaned, hard, non-porous surfaces when thoroughly wipe by a saturated towelette and allowed to remain wet for an exposure time of 1 minute.

However, additional information/data are required to complete the report.

#### 202.3 Additional Information/Data Required to Support Efficacy

- A. The applicant needs to provide the actual preparation date of each of the three (3) batches tested, and the actual test dates of the three (3) test samples when the efficacy data were generated.
- B. The submitted reports show only documentation for subcultured glass slides, however no documentation for subcultures of liquid expressed towelettes. This information should be provided to the agency for *S. choleraesuis*, *S. aureus*, *Ps. aeruginosa*, and *Trichophyton mentagrophytes*.
- C. Since the submitted fungicidal efficacy data developed for lot #H075-B showed borderline effectiveness for a 1 minute exposure time, the applicant needs to provide a clarification/information to the agency as to what revisions or modifications were made that resulted in a failure on the first test and a pass on the second test run.

- D. A review of the applicant's file show that the tuberculocidal data have not satisfied the agency efficacy data requirements. Refer to 203.0 for the specific data requirements to support the proposed one minute tuberculocidal claim.

#### 203.0 Labeling Comments

The proposed comments are applicable for the product "Isotex 70 Disinfecting Towelettes".

- A. On the front panel, the tuberculocidal claim is unacceptable, unwarranted, and must be deleted from the label. The tuberculocidal data requirements have not been met. Tuberculocidal data must be generated by the AOAC Germicidal Spray Test Method (carrier based tests) on each Of 2 samples representing 2 different batches (10 carriers per sample) for a total of 20 carriers. For guidance, refer to the agency deficiency letter dated 08-09-96. Until the data requirements are met, the tuberculocidal claim for a one minute contact time is considered unwarranted, unacceptable and must be removed from the proposed label.

- B. On back panel, there are no adverse comments.