

2-4-98

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

EPA Registration NO.: 10492-4
Date EPA Received 09-29-97
Date RASSB Received: 11-17-97
Project Return Date: 02-02-98
Review Start Date: 02-03-98
Review Completion Data: 02-04-98
MRID No (s): 443903-01
Product Manager/Reviewer & Team No. : Swindell/Terry
Product Name: Isotex 70 Disinfecting Towelettes
Company Name: Palmero Health Care

29104

202.0 RECOMMENDATIONS

202.0 Claims Related to Human Health

202.1 EFFICACY SUPPORTED BY THE DATA

The submitted microbiological data developed by a simulated use test modification of the AOAC Germicidal Spray Products Method (i.e., glass slides) wiped with towelettes (liquid expressed from the used towelette was subcultured) appear adequate to support the product effectiveness as a disinfectant against Escherichia coli on clean, hard, non-porous surfaces which are thoroughly wet by the towelette following a 1 minute exposure time.

However, the acceptance is pending as specified below in 203.0 under label comments.

203.0 LABELING

The following comments are applicable for the proposed label pinpunched 09-30-97.

The following comments are applicable for the front panel of the proposed label. The proposed label reflects a tuberculocidal claim for a 1 minute exposure time which must be removed and replaced with a tuberculocidal label claim for a 5 minute exposure time.

The submitted label is not acceptable. The applicant's needs to resubmit product proposed label without the 1 minute exposure time for Mycobacterium bovis (BCG). Until the applicant's resubmits revised labels without the 1 minute contact time, we have determined that the product label cannot be provided a complete label review.

Until the applicable revisions are made and resubmitted to the agency for a review, the proposed submission is considered incomplete, deficient and unacceptable.

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