EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW
ANTIMICROBIAL PROGRAM BRANCH

IN 11/25/92 OUT 05/13/93

EPA Reg. No. or File Symbol 10492-4
Date Division Received 12-15-92
Type Product (s) Hospital towelette (Saturated Towelette)
MAID No (s) 425742-01 to 425742-04
Product Manager PM 31 (Lee)
Product Name Isotex 70 Disinfecting Towelettes
Company Name Palmero Sales Company, Inc.
Submission Purpose Amendment to add additional efficacy claims with efficacy data and revised label
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

Recommendations

Efficacy Supported by the Data: ⊛ See next page (3pp)

The submitted AOAC Use Dilution Test data appear acceptable to support effectiveness of the product as a hospital and/or general disinfectant against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa when used undiluted on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 6 minutes at 20°C. However, the following information is required: Is it a routine practice in your laboratory to dilute the inocula prior to use in efficacy tests?

Also, the submitted Quantitative Tuberculocidal Test data appear acceptable to support effectiveness of the product as a tuberculocide when used undiluted on precleaned, hard, non-porous surfaces for a contact time of 30 seconds at 20°C. However, the following information is required to complete the data report: Explain how test inoculum was grown/prepared.

Also, the submitted AOAC Fungicidal Test data appear acceptable to support effectiveness of the product as a fungicide when used undiluted on precleaned, hard, non-porous surfaces for a contact time of 4 minutes at 20°C.

Also, the submitted Virucidal Test data appear acceptable to support effectiveness of the product as a virucide against Herpes simplex Type 2 and Adenovirus Type 2 when used undiluted on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 1 minute at 20°C.

Labeling: ⊛ see next page (3.v.)

On the Front Panel revise "Effective...Salmonella choleraesuis" to read "Effective...Salmonella choleraesuis in 6 minutes at 20°C."

On the Front Panel at the end of the sentences "Kills Mycobacterium..." and "Effectively fungicide...." add "on precleaned surfaces."

Srinivas Gowda

Reviewed by Srinivas Gowda Date 05/13/92

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Labeling: (Cont'd)

One-step tuberculocidal and fungicidal label claims are restricted to products of such nature that they may be used to flood the area being treated so that it can remain wet for a minimum of ten minutes. Towelettes are not suitable for this purpose. Therefore tuberculocidal and fungicidal label claims are not permitted on disinfectant towelette labels.

Towelettes by their nature are suitable for sanitization, disinfection and virucidal claims only on precleaned hard nonporous surfaces. This is applicable only to towelettes containing sufficient fluid to flood the area being treated.

The above label contact times are required for the protection of public health regardless of what laboratory data contact times are developed for the product.

Note to P.M.:

The comments on the previous page by Srinivas Gowda are valid, but the registrant does not need to respond to the tuberculocidal and fungicidal data discrepancies since the requested label tuberculocidal and fungicidal language is not permissible for towelettes even with well developed laboratory data.

Before a hospital disinfection claim can be allowed, data developed according to the AOAC protocol will have to be developed. The submitted data used an unapproved modification of the AOAC test (dilution of test organisms).

Z. Vaituzis 7/19/93

Z. Vaituzis, Ph.D.,
Head, EETMS

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