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INCOMPLETE APPLICATION

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
Antimicrobial Program Branch

IN 09/20/89 OUT 09/29/89

EPA Reg. No. or File Symbol 1130-6

Date Application Received 06-27-89

Type Product Hospital Towelette (Saturated Towelette)

MRID No.(s) 411462-02 & 411462-03

Product Manager PM 31 (Lee)

Product Name Burnishine® Germicidal Cloth

Company Name Burnishine Products

Submission Purpose Amendment to add disinfecting claims with a 30 second contact time; & Shelf-life stability testing after 100 cloths have been removed and a 30 day latency period with efficacy data.

Active Ingredient(s): %

n-Alkyl (68% C_{12}, 32% C_{14})
dimethyl ethylbenzyl ammonium chlorides.....0.14

n-Alkyl (60% C_{12}, 30% C_{16}, 5% C_{12}, 5% C_{18})
dimethyl benzyl ammonium chlorides.....0.14

Recommendations:

The application is incomplete for the following reasons:

a. The data were derived on only two of the three required batch samples.

b. Insufficient number of carriers were tested (30 instead 180 carriers/sample).

Additional Data Required to Initiate Review:

If the product is intended for use at exposure periods shorter than those recommended on the label, three samples representing three different batches (one of which is at least 60 days old), each with sixty carriers must be tested against S. choleraesuis ATCC 10708, S. aureus ATCC 6538, and P. aeruginosa ATCC 15442. (180 carriers per sample; a total of 540 carriers). Method must be modified to include 5% blood serum as indicated in 4, 6, & 7 of DIS/TSS-2 enclosures.

Labeling:

No Labeling was submitted.

Srinivas Gowda WEC 10/5/89

Reviewer: Srinivas Gowda Date 09/29/89