7-21-88

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - II

Antimicrobial Program Branch

EPA Petition or File Symbol 1130-6

Date Division Received 07-21-88

MRID Nos. 403839-01, 403839-02, 406352-01 & 407493-01 to 407493-04

Product Manager 31 (Lee)

Product Name Burnishine® Germicidal Cloth

Company Name Burnishine Products

202.0 Recommendations

202.1 Efficacy Supported By The Data

a. The submitted data are adequate to support effectiveness of the product as a "one-step" cleaner-disinfectant for hospital/general use against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa in the presence of moderate amounts of organic soil (5% blood serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 5 minutes for a single use.

b. The submitted data are adequate to support effectiveness of the product as a tuberculocide against Mycobacterium bovis in the presence of moderate amounts of organic soil (5% blood serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 10 minutes at 20°C for a single use. However, varification must be provided to show that confirmatory tuberculocidal tests were performed in the presence of 5% blood serum.

c. The submitted data are adequate to support effectiveness of the product as a virucide against Herpes Simplex Type 2 and Influenza A_2/ Hong kong in the presence of moderate amounts of organic soil (10% Fetal bovine serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 30 seconds for a single use.

d. The submitted data are adequate to support effectiveness of the product as a virucide against Poliovirus-1 in the presence of moderate amounts of organic soil (10% Fetal bovine serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 3 minutes for a single use.

203.0 Labeling

a. For tuberculocidal claim wording must be provided to specify that the product is "Effective in 10 minutes at 20°C".