

11-17-89

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - II

Antimicrobial Program Branch

EPA Reg. No. or File Symbol 777-TE

Date Division Received 11-17-89

MRID No.(s) 41205005, 1-26

Product Manager No. PM 32 (KEMPTER)

Product Name(s) BIOSOL

Company Name(s) Lehn & Fink Products Group

202.3 Additional Data Required to Support Efficacy Data:

1. Exposure temperature should be provided for the test standards (S. cholerasuis, S. aureus, P. aeruginosa) tested with the regular/original scent; exposure time and temp. should be provided for all additional organisms tested with the regular/original scent and for confirmatory data generated with the fresh and light scent alternate formulations; exposure temp. should be provided for tuberculocidal data, fungicidal data and fungistatic data (both non-porous and fabric surfaces).
2. ATCC numbers should be provided for the S. cholerasuis, S. aureus and P. aeruginosa strains utilized in the basic efficacy testing with the regular/original scent product.

203.0 Labeling

1. The product label includes the claim that Biosol is efficacious against "Herpes Simplex Virus Types 1 & 2". No efficacy data has been submitted for HSV Type 2; therefore, the claim must either be eliminated from the label, or efficacy data must be submitted to support this claim.
2. On page 3 of labeling information:
  - "Rhino-39" should read "Rhinovirus-39";
  - "Influenza A2 (Japan)" should read "Influenza A2/Japan/305/57" - ("ATCC VR-100" may be included);
  - "Influenza Type B (Hong Kong)" should read "Influenza B/Hong Kong/5/72, ATCC VR-791"
  - "Adeno Type 2" should read "Adenovirus Type 2";
  - "Rotavirus" should read "Rotavirus Wa".

202.2 Recommendations

202.1 Claims Related to Human Health:

202.1.1. Acceptable Claims: The submitted efficacy data are acceptable to support the product's claim as an aerosol disinfectant against the following organisms:

Salmonella choleraesuis  
Staphylococcus aureus  
Pseudomonas aeruginosa  
Shigella dysenteriae  
Escherichia coli  
Proteus vulgaris  
Proteus mirabilis  
Enterobacter aerogenes  
Klebsiella pneumoniae  
Salmonella enteritidis  
Pseudomonas cepacia  
Streptococcus faecalis

Corynebacterium diphtheriae  
Staphylococcus epidermidis  
Salmonella schottmuelleri  
Streptococcus pyogenes  
Serratia marcescens  
Pseudomonas putida  
Salmonella paratyphi  
Campylobacter jejuni  
Listeria monocytogenes  
Streptococcus salivarius  
Neisseria elongata

Rhinovirus 39  
Influenza A2/Japan/305/57 (ATCC VR-100)  
Influenza B/Hong Kong/5/72 (ATCC VR-791)  
Herpes Simplex Virus Type I  
Adenovirus Type II  
Vaccinia Virus (Wyeth Strain)  
Poliovirus Type I (Chat Strain, ATCC VR-192)  
Rotavirus (Wa)  
Respiratory Syncytial Virus (Long Strain)

Candida albicans  
Aspergillus niger  
Trichophyton mentagrophytes

Mycobacterium tuberculosis var. bovis

The product is effective in aerosol form at the use-dilution provided in the presence of a 5% organic soil load when used on non-porous surfaces for a contact time of 10 min.

202.2 Claims not related to human health:

202.2.1 Acceptable Claims: The product is effective in aerosol form as a fungistatic agent, in the presence of a 5% organic soil load, against Aspergillus niger for up to 30 days on a hard, non-porous surface (contact time = 3 min) and against Aspergillus niger and Penicillium variable for up to 14 days on a fabric surface (contact time = 3 min).