

AMENDMENT
EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW

ANTIMICROBIAL PROGRAM BRANCH

IN 10/06/94 OUT 10/21/94

EPA Reg. No. or File Symbol 51267-1
EPA Petition or EUP No. None
Date Division Received 09-21-94
Type Product Hospital Disinfectant
Accession No. 433806-01 and 433806-02
Product Manager PM 31 (Swindell)
Product Name Bioclean
Company Name Bioserve, Inc.
Submission Purpose Amendment to add tuberculocidal claims
against Mycobacterium tuberculosis with
efficacy data and revised propose label
Type Formulation Liquid

Active Ingredient (s):

%

69104 n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)
69154 dimethyl benzyl ammonium chloride.....5.0
83001 n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl
ammonium chloride.....5.0
Bis (tributyltin) oxide.....1.0

Recommendations:

The submitted data are acceptable to support effectiveness of the product as a tuberculocide against Mycobacterium bovis (BCG) at a 1:128 dilution on precleaned, hard, nonporous surfaces for a contact time of 5 minutes at 20°C.

Labeling: Add the FDA/EPA MOW disclaimer statement (zu)

Change "Mycobacterium tuberculosis" to read "Mycobacterium bovis (BCG)" wherever it appears on the label.

Reviewed by Srinivas Gowda Date 10/21/94

[Signature]

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