

UNDATED

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 5741-ER

Date Division Received 10-05-87

Data Accession No.(s) 402773-01, 402773-02 & 402773-03

Product Manager No. PM 31 (Lee)

Product Name BIO-CLEAN Cleaner/Disinfectant Deodorizer

Company Name Bioserv, Inc.



202.0 Recommendations

202.1 Efficacy Supported by the Data:

- a. The submitted data are acceptable to support effectiveness of the product, as a hospital/general disinfectant against Pseudomonas aeruginosa, Staphylococcus aureus, and Salmonella choleraesuis, when used at a 1:128 dilution on hard, non-porous surfaces for a contact time of 10 minutes at 20°C in the presence of 5% blood serum.
- b. The submitted fungicidal data are acceptable to support effectiveness of the product as a fungicide against Trichophyton mentagrophytes (pathogenic fungi) when used undiluted in the presence of 5% blood serum at a contact time of 10 minutes at 20°C. However, the amount of inoculum should be provided. Refer to 202.2 below.
- c. The submitted tuberculocidal data are acceptable to support effectiveness of the product as a tuberculocide against Mycobacterium bovis (BCG) when used undiluted in the presence of 5% blood serum at a contact time of 10 minutes. However, acceptance is pending upon the submission of additional data as indicated in 202.2 below.
- d. The submitted virucidal data are acceptable to support effectiveness of the product against Herpes Simplex Type 2 and Influenza A2/Hong Kong when used at a 200 ppm concentration of active ingredients for a contact time of 10 minutes.

202.2 Additional Data/Information Required to Support Efficacy:

- a. In the fungicidal testing submit the initial amount of inoculum per carrier. For the Efficacy Data Requirements refer to DIS/TSS-6 enclosure, item 3.
- b. To support the tuberculocidal claim, validation data must be developed and submitted by testing one additional sample of the product by a laboratory other than the laboratory which developed the original data using the same test procedure and the same test conditions as the original laboratory. For additional testing requirements refer to the attached Tuberculocidal Data-Call-In Notice dated 06-13-86.

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