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TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Petition or File Symbol 1130-6

Date Division Received 10-20-87

Data Accession No. 403839-01, 403839-02, & 406352-01

Product Manager 31 (Lee)

Product Name Burnishine® Germicidal Cloth

Company Name Burnishine Products

202.0 Recommendations

202.1 Inadequate Data/Information

a. The submitted bactericidal data developed by the modified A.O.A.C. Germicidal Spray Products Test Method (glass slide wiped 10 times with towelette) in the presence of 5% blood serum against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa for a 5 minutes contact time are inadequate because:

1. The data were developed on only one of the two required batch samples.

2. Contaminated carrier drying time and temperature was not specified.

b. The submitted tuberculocidal data developed by the Modified A.O.A.C. Germicidal Spray Products Test in the presence of 5% blood serum against Mycobacterium bovis for a 10 minute contact time 20°C are inadequate because:

1. Complete procedural information for towelette testing was not provided.

c. The submitted tuberculocidal data developed by the Pre-Saturated or Impreganted Towelettes for Hard Surface Disinfection/A.O.A.C. Germicidal Spray Products Test in the presence of 5% blood serum against Mycobacterium bovis for a 10 minute contact time 20°C are inadequate because:

1. Complete procedural information for towelette testing was not provided.

d. The submitted confirmatory tuberculocidal data (validation data) developed by the Pre-Saturated or Impreganted Towelettes for Hard Surface Disinfection Method against Mycobacterium bovis for a 10 minute contact time 20°C are inadequate because:

1. Complete procedural information for towelette testing was not provided.

2. Test report did not include phenol resistance of Mycobacterium bovis.

3. Also, survival of inoculum on control carriers after drying were not reported.

e. The submitted Sanitizing data developed by the Pre-Saturated or Impreganted Towelettes for Hard Surface Disinfection/A.O.A.C. Germicidal Spray Products Test in the presence of 5% blood serum against Klebsiella pneumoniae for a 5 minute contact time at 20°C are inadequate because:

1. Complete procedural information for towelette testing was not provided.

2. Data were not developed against Staphylococcus aureus under the above test conditions to support efficacy of this product as a sanitizer for non-food contact surfaces in general use areas.
3. The procedure used to insure neutralization of the germicide in subcultures was achieved not specified.

f. The submitted virucidal data are not adequate or acceptable to support effectiveness of the product as virucides against Herpes Simplex Virus Type 2 and Influenza Type A_2/Hong Kong on inanimate surfaces.

The submitted data/test report were difficient with respect to the following:

1. Volume of virus suspension inoculated and surface area of the petri dish were not reported.

2. Time, temperature, and exposure conditions employed in the drying procedure were not reported.

3. Method (s) used in propagating the virus stock and composition of the virus inoculum were not reported.

4. Time and temperature employed during incubation of subcultures were not reported.

5. Data showing quantitative survival of the viruses on hard, surface carriers before and after drying under specified conditions were not reported.

6. Specific descriptions of the method employed for quantitative assay of the infective virus (ID-50), including host cell system used, and the details of the assay procedure were not provided.

7. The manufacturing dates (s), and test date(s) for the product samples were not provided.

8. Technique employed to "resuspend" the virus film after the disinfectant treatment were not reported.

9. Maintainance media/Diluent/Recovery media/Neutralizer employed were not reported.

10. The test results indicating "Percent Inactivation >99.9" requires further explanation. It is not clear whether the results mean that virus was detected or was not detected.

11. Virus control titres(TCID-50: 10E7.5/ml), toxicity control titres (10E2.5/ml), and virus inactivation (10E4.0/ml) are same for all test viruses. Provide explanation.

12. It is not clear if the data were developed by Modified A.O.A.C. Germicidal Spray Products Test Method or Use-dilution Test, modified for testing the towelette. Please clarify. Also, submit complete procedural information for towelette testing.

202.2 Additional Data Required To Support Efficacy

a. To support effectiveness of this product for the patterns of use indicated on the proposed label, the following additional data are required:

1. To support "one-step" disinfectant-cleaner claims for moderately soiled hard, non-porous surfaces, data must be developed on another batch sample in the presence of 5% blood serum at 5 minutes contact time by a modified A.O.A.C. Germicidal Spray Products Test method for towelette testing. Refer to the attached Efficacy Data Requirements for Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection, item no. (c) of DIS/TSS-1, and item nos. 4, 6, 7, & 8 of DIS/TSS-2 enclosures.

2. For tuberculocidal test reports and sanitizing test report submit complete procedural information for testing the towelette.

3. To support sanitizing claims for treating moderately soiled non-food contact surfaces at 5 minutes contact time, data must be developed against Staphylococcus aureus in the presence of 5% blood serum as indicated in the attached DIS/TSS-10 enclosure/Pre-Saturated or Impregnated Towelettes for Hard Surface Disinfection.

4. In the sanitizing test report specify the procedure used to insure neutralization of the germicide in subcultures was achieved.

5. To support virucidal claims against Herpes Simplex Type 2 and Influenza A_2/Hong Kong additional data/ procedural information as indicated in 202.1 (~~f~~) above must be submitted.

6. For confirmatory tuberculocidal test reports (validation data) submit complete procedural information for towelette testing, phenol resistance of test microorganism (actual test results), and control carrier counts after drying.

203.0 Labeling

Labeling review cannot be completed until the required additional data/informations are submitted.