

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -I

ANTIMICROBIAL PROGRAM BRANCH

IN 1-6-95 OUT 1-24-95

Reviewed by M. Michael Nieves Date 1-24-95
EPA Reg. No. or File Symbol 9480-U
EPA Petition or EUP No. None
Date Division Received 12-6-94
Type Product Disinfectant Towelettes
MRID No(s) 434745-01, 434745-02, 434745-03
Product Manager Walter Francis (PM 31)
Product Name Sani-Cloth Germicidal Wipes
Company Name Nice-Pak Products Inc.
Submission Purpose The submission is an application for new registration with efficacy data and proposed label.
Type Formulation Impregnated Towelettes

Active Ingredients(s)

n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl
ammonium chloride..... .25%
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl
benzyl ammonium chloride..... .25%
Isopropyl alcohol..... 55%

200.0 **Introduction:**

200.1 **Uses:**

See attached proposed label dated 9-8-1994.

200.2 **Background Information:**

The submission is an application for new registration with efficacy data and proposed label.

200.3 **Factors Affecting Amount/Type of Data Required:**

None

201.0 **Data Summary**

None

201.1 **Abstract of Test Reports:**

None

201.2 **Brief Description of Tests:**

1. "Quantitative Tuberculocidal Suspension Test for Determining the Efficacy of Nice-Pak Products, Inc. Sani-Cloth Germicidal Wipes Against Mycobacterium bovis BCG" by Larry N. Wilson and William J. Suling of Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205; dated July 13, 1994 (MRID No. 434745-01).

2. "AOAC Use-Dilution Test for Determining the Efficacy of Nice-Pak Products' Sani-Cloth Germicidal Wipes Against Pseudomonas aeruginosa ATCC 15442, Salmonella choleraesuis ATCC 10708 and Staphylococcus aureus ATCC 6538" by Larry N. Wilson and William J. Suling of Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205; dated September 9, 1994 (MRID No. 434745-02).

3. "AOAC Use-Dilution Test for Determining the Efficacy of Nice-Pak Products' Sani-Cloth Germicidal Wipes Against Methicillin-resistant Staphylococcus aureus ATCC 33591" by Larry N. Wilson and William J. Suling of Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205; dated September 9, 1994 (MRID No. 434745-03).

201.3 **Data Summaries**

None

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201.4 **Other Summarized Results:**

See Recommendations under 202.0.

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Product Manager Walter Francis (PM 31)

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202.0 Recommendations

202.1 Efficacy Supported By The Data:

1. "Quantitative Tuberculocidal Suspension Test for Determining the Efficacy of Nice-Pak Products, Inc. Sani-Cloth Germicidal Wipes Against Mycobacterium bovis BCG" by Larry N. Wilson and William J. Suling of Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205; dated July 13, 1994 (MRID No. 434745-01).

The submitted efficacy data (MRID No. 434745-01) appear adequate to support effectiveness of the product as a tuberculocide against Mycobacterium bovis BCG in the presence of 5% blood serum for a contact time of 1 minute at 20°C. *(a 5 min. label contact time according to EPA published methodology)*

2. "AOAC Use-Dilution Test for Determining the Efficacy of Nice-Pak Products' Sani-Cloth Germicidal Wipes Against Pseudomonas aeruginosa ATCC 15442, Salmonella choleraesuis ATCC 10708 and Staphylococcus aureus ATCC 6538" by Larry N. Wilson and William J. Suling of Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205; dated September 9, 1994 (MRID No. 434745-02).

The submitted efficacy data (MRID No. 434745-02) appear adequate to support effectiveness of the product as a Hospital Disinfectant against Pseudomonas aeruginosa ATCC 15442, Salmonella choleraesuis ATCC 10708 and Staphylococcus aureus ATCC 6538 in the presence of 5% blood serum for a contact time of 5 minutes at 20°C.

3. "AOAC Use-Dilution Test for Determining the Efficacy of Nice-Pak Products' Sani-Cloth Germicidal Wipes Against Methicillin-resistant Staphylococcus aureus ATCC 33591" by Larry N. Wilson and William J. Suling of Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205; dated September 9, 1994 (MRID No. 434745-03).

The submitted efficacy data (MRID No. 434745-03) appear adequate to support effectiveness of the product as a Hospital Disinfectant against Staphylococcus aureus ATCC 33591 in the presence of 5% blood serum for a contact time of 5 minutes at 20°C.

Labeling:

The proposed label is unacceptable. The label review cannot be completed until the deficiencies mentioned below are addressed by the registrant:

1. Remove all disinfectant claims against the following microorganisms:

- *Klebsiella pneumoniae*
- Influenza A2/HK
- Herpes Simplex II Virus
- Polio I Virus
- Rhinovirus
- Canine Distemper
- Pseudorabies Virus
- Vaccinia Virus
- Adeno Virus Type 5
- Human immunodeficiency virus Type I (HIV-1)
- *Trichophyton mentagrophytes*
- *Aspergillus niger*
- *Candida albicans*

2. Remove all general "Fungicidal" and "Virucidal" claims.

3. Remove all "Special Instructions for Cleaning and Decontamination Against HIV-1 (AIDS Virus) for Surfaces or Objects Soiled with Blood or Body Fluids".

4. If the registrant is citing data from another registrant to support the above claims, he must submit the appropriate data references.

5. The basic support data references for the basic three organisms must also be submitted. The confirmatory data submitted even though acceptable require ~~the~~ specific references to the supporting data developed for the original product.

Note: confirmatory data is not a replacement for the basic efficacy data required for all public health products.