

NEW APPLICATION

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - I

ANTIMICROBIAL PROGRAM BRANCH

IN 07/26/95 OUT 09/21/95

Srinivas Gowda
Reviewed by Srinivas Gowda Date 09/21/95
EPA Reg. No. or File Symbol 9480-U
Date Division Received 06-13-95
Type Product Hospital Disinfectant Wipe
MRID No (s) 436964-02 to 436964-10
Product Manager PM 31 (Johnson)
Product Name Sani-Cloth Germicidal Wipes
Company Name PDI Inc.
Submission Purpose New Application with efficacy data and label
Type Formulation Pre-Saturated Towelette

<u>Active Ingredient (s):</u>	<u>%</u>
n-Alkyl (68% C12, 32% C14)	
dimethyl ethylbenzyl ammonium chloride.....	0.25
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18)	
dimethyl benzyl ammonium chloride.....	0.25
Isopropyl alcohol.....	55.00

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW - II

ANTIMICROBIAL PROGRAM BRANCH

EPA Reg. No. or File Symbol 9480-U

Date Division Received 06-13-95

Type Product Hospital Disinfectant Wipe

MRID No (s) 436964-02 to 436964-10

Product Manager PM 31 (Johnson)

Product Name Sani-Cloth Germicidal Wipes

Company Name PDI Inc.

202.0

Recommendations

202.1

Efficacy Supported by the Data:

1. "AOAC Use Dilution Test for Determining the Efficacy of Nice-Pak Products Inc. Sani-Cloth Germicidal Wipes Against *Klebsiella pneumoniae* ATCC 4352" by Larry N. Wilson and William J. Suling, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205, dated May 4, 1995 (MRID No. 436964-02).

The submitted data developed by the AOAC Use Dilution Test Method appear acceptable to support effectiveness of the product as a disinfectant against *Klebsiella pneumoniae* ATCC 4352 in the presence of moderate amounts of organic soil (5% blood serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 4 minutes at 20°C for a single use.

2. "Virucidal Efficacy of Nice-Pak Products Inc.'s Sani-Cloth Germicidal Wipes Against the Influenza A2/Hong Kong Virus" by Bonnie J. Bowden, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205, dated May 31, 1995 (MRID No. 436964-03).

The submitted data developed by the EPA's Virucidal Test Method appear adequate to support effectiveness of the product as a virucide against Influenza A2/Hong Kong ATCC VR-544 in the presence of moderate amounts of organic soil (5% fetal bovine serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 1 minute at 26°C (room temperature) for a single use.

3. "Virucidal Efficacy of Nice-Pak Products Inc.'s Sani-Cloth Germicidal Wipes Against the Herpes Simplex Type 2" by Bonnie J. Bowden, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205, dated May 31, 1995 (MRID No. 436964-04).

The submitted data developed by the EPA's Virucidal Test Method appear adequate to support effectiveness of the product as a virucide against Herpes simplex Type 2 ATCC VR-734 in the presence of moderate amounts of organic soil (5% fetal bovine serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 1 minutes at 27°C (room temperature) for a single use.

4. "Virucidal Efficacy of Nice-Pak Products Inc.'s Sani-Cloth Germicidal Wipes Against the Rhinovirus" by Bonnie J. Bowden, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205, dated May 30, 1995

(MRID No. 436964-05).

The submitted data developed by the EPA's Virucidal Test Method appear adequate to support effectiveness of the product as a virucide against Rhinovirus ATCC VR-1110 in the presence of moderate amounts of organic soil (5% fetal bovine serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 1 minutes at 25°C (room temperature) for a single use.

5. "Virucidal Efficacy of Nice-Pak Products Inc.'s Sani-Cloth Germicidal Wipes Against the Pseudorabies Virus" by Bonnie J. Bowden, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205, dated May 30, 1995 (MRID No. 436964-06).

The submitted data developed by the EPA's Virucidal Test Method appear adequate to support effectiveness of the product as a virucide against Pseudorabies ATCC VR-135 in the presence of moderate amounts of organic soil (5% fetal bovine serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 1 minutes at 26°C (room temperature) for a single use.

6. "Virucidal Efficacy of Nice-Pak Products Inc.'s Sani-Cloth Germicidal Wipes Against the Vaccinia Virus" by Bonnie J. Bowden, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205, dated May 30, 1995 (MRID No. 436964-07).

The submitted data developed by the EPA's Virucidal Test Method appear adequate to support effectiveness of the product as a virucide against Vaccinia ATCC VR-1354 in the presence of moderate amounts of organic soil (5% fetal bovine serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 1 minutes at 26°C (room temperature) for a single use.

7. "Virucidal Efficacy of Nice-Pak Products Inc.'s Sani-Cloth Germicidal Wipes Against the Adenovirus Type 5" by Bonnie J. Bowden, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205, dated May 30, 1995 (MRID No. 436964-08).

The submitted data developed by the EPA's Virucidal Test Method appear adequate to support effectiveness of the product as a virucide against Adenovirus Type 5 ATCC VR-5 in the presence of moderate amounts of organic soil (5% fetal bovine serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 1 minutes at 25°C (room

4

temperature) for a single use.

8. "Virucidal Efficacy of Nice-Pak Products Inc.'s Sani-Cloth Germicidal Wipes Against the HIV-1" by Bonnie J. Bowden, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205, dated May 30, 1995 (MRID No. 436964-09).

The submitted data developed by the EPA's Virucidal Test Method appear adequate to support effectiveness of the product as a virucide against HIV-1 (AIDS virus) RF strain in the presence of moderate amounts of organic soil (5% fetal bovine serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 1 minutes at 22°C (room temperature) for a single use.

9. "AOAC Use Dilution Test for Determining the Efficacy of Nice-Pak Products Inc. Sani-Cloth Germicidal Wipes Against *Candida albicans* ATCC 11651" by Larry N. Wilson and William J. Suling, Southern Research Institute, 2000 Ninth Avenue South, Birmingham, AL 35205, dated May 4, 1995 (MRID No. 436964-10).

The submitted data developed by the AOAC Use Dilution Test Method appear acceptable to support effectiveness of the product as a fungicide against *Candida albicans* ATCC 11651 in the presence of moderate amounts of organic soil (5% blood serum) on hard, non-porous surfaces which are thoroughly wet by the towelette and remain wet for a contact time of 4 minutes at 20°C for a single use.

203.0

Labeling:

The minimum contact time that will be allowed on the label for tuberculocidal effectiveness is 5 minutes if Quantitative Tuberculocidal Test Method is employed. Therefore, on the front panel, revise the statement "Kills *Mycobacterium bovis* BCG (Tuberculosis) in 1 minute at 20°C" to read "Kills *Mycobacterium bovis* BCG (Tuberculosis) in 5 minutes at 20°C".

Change "...Influenza A2/HK..." to read "Influenza A2 Hong Kong..."

Note To PM: resubmit label for review after
required changes are incorporated.

Z. Williams
EEH/S
9/26/95