EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION

EFFICACY REVIEW -I

ANTIMICROBIAL PROGRAM BRANCH

IN 07/24/96 OUT 07/31/96

Reviewed by Srinivas Gowda Date 07/31/96
Z. Vaituzis

LAN Code 9480-4.607

EPA Reg. No. or File Symbol 9480-4

Date Division Received 07-07-96

Type Product (s) Hospital towelette (Saturated Towelette)

MAID No (s) 440499-01 to 440499-02

Product Manager PM 31 (Johnson)

Product Name Sani-Cloth Germicidal Wipes

Company Name Nice-Pak

Submission Purpose Amendment to add additional efficacy claims against Vancomycin-Resistant Enterococcus faecalis and Escherichia coli with efficacy data and revised label

Type Formulation Single Use Disposable Towelette Saturated with ready-to-use liquid

Active Ingredient (s): %

n-alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chloride.....0.25

n-alkyl (68% C12,32% C14) dimethyl benzyl ammonium chloride..0.25

Isopropyl alcohol.....55.00

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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 Escherichia coli 0157:H7 ATCC 35150" by Larry N. Wilson and William J. Suling, Southern Research Institute, Birmingham, Alabama, dated Jan. 17, 1996 (MRID No. 440499-01)

   The submitted AOAC Use Dilution Test data appear acceptable to support effectiveness of the product as a disinfectant against Escherichia coli 0157:H7 ATCC 35150 when used as undiluted expressed liquid from the towelette on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 5 minutes at 20°C.

2. "AOAC Use Dilution Test for Determining the Efficacy of Nice-Pak Products Inc. Sani-cloth Germicidal Wipes Against Vancomycin-Resistant Enterococcus faecalis ATCC 51299" by Larry N. Wilson and William J. Suling, Southern Research Institute, Birmingham, Alabama, dated Jan. 17, 1996 (MRID No. 440499-02)

   The submitted AOAC Use Dilution Test data appear acceptable to support effectiveness of the product as a disinfectant against Vancomycin-Resistant Enterococcus faecalis ATCC 51299 when used as undiluted expressed liquid from the towelette on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 5 minutes at 20°C.

203.0 **Labeling:**

Note to PM:

Stamp label only after the required changes below have been incorporated.

Comments are applicable to submitted revised label dated June 26, 1996

(See RATIONALE at the end of comments for the basis of the following requirements)

1. On the front panel the claim "Disinfectant Thermometer Wipes" is not acceptable and must be deleted. Thermometers are considered semi-critical instruments (medical devices) and fall under the jurisdiction of Food and Drug Administration. According to the MOU

between EPA-FDA (JUNE 30, 1994 PESTICIDE REGULATION [PR] NOTICE 94-4) only registered sterilants are to be used on medical devices that touch the mucous membranes. Sani-Cloth Germicidal Wipes are not registered as sterilants. (In addition, wiping would not expose the thermometer to the disinfectant for the required contact time to achieve the desired results).

2. According to EPA Antimicrobial Labeling Guidelines (See RATIONALE) the level of antimicrobial activity must be specified in the Directions for Use. Therefore, on the Back Panel, separate "Dispenser Directions" from "Disinfection directions".

3. Remove the words "where required" from Disinfection and Food Contact Surface Disinfection directions. The **Directions for Use** must list the contact time for each type of antimicrobial activity. When one contact time is listed it applies for all label uses [see paragraph (C) in RATIONALE, below].

RATIONALE

(8) Directions for Use. (i) Basic Requirements. (A) Refer to 40 CFR 156.10(i), **Directions for Use** for general requirements and contents of directions for use.

(ii) Additional Requirements. When use directions are required, **labels must bear directions for each recommended category of use and/or level of antimicrobial activity.** (40 CFR 156.10(i)(1)(iii) gives exceptions to the requirement for directions for use.) The directions for use should include the information in paragraphs (A) through (M) below, except in those cases where certain items are not applicable. In addition, products intended for the use patterns specified in § 101-2 through -16 and §§ 102-3 through -7 of this Subdivision should comply with the specific requirements provided therein. Additional instructions, other than those listed below, or contained in § 101-2 through -16 and §§ 102-3 through -7 may be recommended by the applicant, or required by the Agency on a case-by-case basis.

(A) **The level of antimicrobial activity (e.g., sterilization, disinfection, sanitization, bacteriostasis) intended to be provided by the product.** Refer to § 101-1(d) of this Subdivision for terminology concerning levels of antimicrobial activity.

§ 101-1(d):

(5) "Disinfectant" means an agent that eliminates a specific species of infectious or other undesired microorganism, but not necessarily bacterial spores, in the inanimate environment only. The term "disinfection" connotes the combating of an infection whereas "infection" involves only living plants and animals. For the purposes of this section, the environment is considered "contaminated," not "infected", and the term "germicide" and "bactericide" are synonyms for the word "disinfectant."

(6) "Fungicide" means an agent that destroys fungi (including yeasts) and/or fungal spores pathogenic to man or other animals in the inanimate environment.

(7) "Virucide" means an agent that destroys or irreversibly inactivates viruses in the inanimate environment.

Label Claims. (i) The unqualified label claim "virucidal" is not generally acceptable. The claim "virucidal" must be qualified by designating each specific virus against which the product has been tested and shown to be effective. The complete nomenclature of each virus needs to be exhibited on the label [see paragraph (g)(3) of this section]. Causal effects can accompany each virus listed parenthetically [e.g., herpes simplex virus, type 1 (causes cold sores) and herpes simplex virus, type 2 (causes genital herpes)]. It should be indicated that the virucidal activity occurs only on environmental surfaces.

(8) "Tuberculocide" means an agent that destroys or irreversibly inactivates tubercle bacilli **in the inanimate environment. (Note: not liquid culture)**

(C) If the label indicates that the product may be used for more than one level of antimicrobial activity (e.g., sterilization, disinfection, sanitization) there must be separate and distinct directions for use for each level of activity. If the product can be used for different types of antimicrobial activity (e.g., virucidal, tuberculocidal), but the contact time and temperature are the same for each type of activity, separate directions are not necessary. If extended contact times or elevated temperature are required to achieve a specific type of antimicrobial activity (e.g., tuberculocidal) then this guidance must be provided under a separate heading (e.g., Directions for Use as a Tuberculocide) under the Directions for Use.