



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Antimicrobial Division (7510C)  
1200 Pennsylvania Avenue N.W.  
Washington, D.C. 20460

EPA Reg. Number:

9480-7

Date of Issuance:

MAR 08 2004

**NOTICE OF PESTICIDE:**

Registration  
 Re-registration

(under FIFRA, as amended)

Term of Issuance:

**This Notice is time-limited and expires 4/15/04. It supercedes the Notice which expires 3/15/04.**

Name of Pesticide Product:

**SANI-WIPE**

Name and Address of Registrant (include ZIP Code):

PDI,  
Healthcare Division of Nice-Pak Products. Inc.  
Two Nice Pak Park  
Orangeburg, NY 10962

**Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.**

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) providing:

1. You submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

Signature of Approving Official:

Marshall Swindell  
Acting Product Manager 33  
Regulatory Management Branch 1  
Antimicrobial Division (7510C)

Date:

MAR 08 2004

2. The efficacy data (under review) you submitted to support the food contact use sites and associated organisms listed on the attached label, using the testing requirements outlined in the "Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes", and the data (under review) you submitted for each organism intended for non-food contact use sites using DSS/TSS #10, are found fully acceptable.

3. You must make the changes listed below to the "Master Label" (your version dated 3/26/03), and submit three copies of a final printed "Master Label" within 60 days of the date on this notice.

A. The label uses brackets around "[Total...100.0000%]" indicating that this is an optional statement. The Agency will accept brackets on an interim basis providing: (1) you submit acceptable supporting evidence that "...labeling would include 'total' where there was room but that some labels are small and PDI needs to have the option of leaving it off ...", and (2) that you are not deleting this statement simply to make room and space for optional marketing claims or other optional words.

B. The boxes at the bottom of each page enclose identical "label reader rules" that are not intended to be on final labels. You must make the following global changes to each of these boxes:

1. Delete "top" from the first boldfaced line as there are no top boxes for reader rules.

2. Change "The terms 'Wipe(s)', 'Towel(s)', and 'Cloth(s)' can be used interchangeably throughout", to the following, "The terms 'Wipe(s)', 'Towel(s)', and 'Cloth(s)' can be used interchangeably throughout except for the product primary brand name which can be only changed by notification or amendment."

3. Change "List of items can be used partially or in their entirety", to, "List of uses and use sites can be used partially or in their entirety. Any individual statement, claim, restriction or other wording must be used in its entirety, and can not be expanded or shortened by combination, partial deletion, merging, or similar".

C. On page 2/5, under "Food Contact Surfaces", change "Thoroughly preclean all food contact surfaces following required methods using suitable detergents, brushes, sponges and any other necessary equipment prior to rinsing and sanitizing with Sani-Wipe[...]", to "Thoroughly preclean all food contact surfaces following required methods using suitable detergents, brushes, sponges and any other necessary equipment. Then rinse with potable water and sanitize with Sani-Wipe[...]" This clarifies that rinsing is not with the product itself.

4. To clarify and resolve concerns with small size labels not having space for a "Total" statement (requirement 4A above), during the time-limited duration of this product, you must submit two copies of actual full color production labels for small product sizes that you intend to put into the marketplace.

5. The required label changes listed herein and the submitted data referenced in item #2 above, must be found to be fully acceptable for EPA to change the "Terms of Issuance" of this registration. If any of the submitted data are found to be not acceptable, you will be required to delete the affected portions of the label. Your release for shipment of the product constitutes acceptance of all conditions listed herein.

A copy of the "Master Label", stamped "Accepted with comments", is attached for your records. This label supercedes all prior label versions. If you have any questions concerning this letter, please contact myself at 703-308-6341, or Tony Kish at (703) 308-9443.

Sincerely,



Marshall Swindell  
Product Manager 33  
Regulatory Management Branch 1  
Antimicrobial Division (7510C)

Enclosure

[FRONT PANEL]

\*SANI-WIPE®

\*NO RINSE HARD NONPOROUS SURFACE SANITIZING WIPE

[FOOD CONTACT SURFACES]

[Designed for sanitizing precleaned hard nonporous food contact surfaces where the control of cross contamination between treated surfaces is of prime importance]

\*99.999% effective in 60 seconds against Staphylococcus aureus (ATCC #6538), Escherichia coli (ATCC# 11229) and Shigella boydii (ATCC#9207) on food contact surfaces.

[For use in retail and institutional food establishments, food processing plants and other health department regulated food facilities.]

[Pre-measured, pre-moistened sanitizing wipes for use on hard nonporous surfaces.]

\*ACTIVE INGREDIENTS

- \*n-Alkyl(C<sub>17</sub>,67%, C<sub>14</sub>,25%, C<sub>16</sub>,7%, C<sub>8</sub>, C<sub>10</sub>, C<sub>18</sub>,1%) Dimethyl Benzyl
- \*Ammonium Chloride.....0.0175%
- \*Isopropyl Alcohol.....5.4800%
- \*OTHER INGREDIENTS .....94.5025%
- [TOTAL .....100.0000%]

\*KEEP OUT OF REACH OF CHILDREN

\*CAUTION

\*See back [side] panel for additional precautionary statements

\*NET WT. [value]

[NET CONTENTS]

\* #OF [Premeasured Premoistened][Wipes or Cloths] SIZE [of each cloth]

\*E P.A. Reg. No.9480 - 7

\*E P.A. Est. No.9480-NY-1

[EPA Est. No. A=9480-NY-1, B=9480-IN-1 Alpha character will precede batch number on product container]

\*PDL The Healthcare Division of Nice-Pak Products, Inc.

\*Two Nice-Pak Park

\*Orangeburg, NY 10962-1376

[Phone:] [Telephone:][Insert phone number]

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

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Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
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9480-7

**THE INFORMATION IN BOXES AT THE TOP AND BOTTOM ARE NOT PART OF THE LABELING**

- \* - Precedes required label elements, (the symbol "" is not required to appear on production labels)
- [ ] - Statements in brackets are optional or instructional. Italicized words in brackets are not included
- Sequence and placement of phrases is optional unless specified in 40 CFR 156.10.
- Capitalization, plurals or singular, bold and italics are all variable unless specified in 40 CFR
- The terms "Wipe(s)", "Towel(s)" and "Cloth(s)" can be used interchangeably throughout
- Lists of items can be used partially or in their entirety

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**[BACK PANEL]**

[Use at least one of the use sites indicated in the paragraph below or in the "For Use In" section below.]

**[AREAS OF USE IN FOOD SERVICE AND FOOD PREPARATION:]**

\*This product is recommended for use in retail food establishments [including [restaurants,] [hotels,] [kitchens,] [airplanes,] [food service in healthcare settings,] [delicatessens,] [supermarkets,] [temporary food establishments,] [food processing plants,] and other food service and food preparation settings where the [control] of the hazards] or [prevention] of cross contamination between treated surfaces is of primary importance.

[Recommended for use on precleaned hard nonporous food contact surfaces in kitchens.]

[Recommended for use on hard nonporous nonfood contact surfaces as a one step sanitizer.]

**[FOR USE IN:]**

- [Restaurants]
- [Food Processing Plants]
- [Hotels]
- [Nursing Homes]
- [Schools]
- [Cafeterias]
- [Airplanes]
- [Caterers]

- [Fast Food Chains]
- [Poultry/Meat Packing Facilities]
- [Motels]
- [Day Care Settings]
- [Nurseries]
- [Healthcare Food Service]
- [Delicatessens]
- [Temporary Food Establishments]

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**\*DIRECTIONS FOR USE:**

\*It is violation of Federal law to use this product in a manner inconsistent with its labeling.

[Thoroughly preclean if surface is visibly soiled.] [Product is ready for use, no mixing or measuring required.]

**[FOR USE ON**

Hard nonporous food contact surfaces.]

\*Do not use to sanitize eating utensils, glassware, cookware, and food processing equipment.

**\*FOOD CONTACT SURFACES**

\*Cleaning and Sanitizing Procedure: Thoroughly preclean all food contact surfaces following required methods using suitable detergents, brushes, sponges and other necessary equipment prior to rinsing and sanitizing with Sani-Wipe [or this product or insert private label product name]. To sanitize, wipe enough for treated area to remain visibly wet for a minimum of 60 seconds. Let air dry. No rinsing is required.

\*For use on precleaned [thoroughly washed] and rinsed hard nonporous food contact surfaces such as counter tops, sanitizer sinks, drain boards, non-wood cutting boards and equipment or utensil surfaces with which food normally contacts including surfaces from which food may drain, drip or splash into a food or onto a surface normally in contact with food.

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[99.999% effective in 60 seconds against Staphylococcus aureus (ATCC #6538), Escherichia coli (ATCC#11229) and Shigella boydii (ATCC#9207) on precleaned, food contact surfaces]

\*Be sure to follow all applicable health inspection agency code requirements for precleaning, rinsing and sanitizing.

\*Do not apply directly to any type of human food.

\*Dispensing: [Choose the dispensing directions from below that correspond to the product package.]

[On canister]

To start feed: Remove lid and discard inner seal from canister. Find center of wipe roll, remove first wipe for use, twist corner of next wipe into a point and thread through the hole in the canister lid. Pull through about one inch. Replace lid. Dispense remaining wipes as necessary by pulling out at an angle. When not in use keep center cap of lid closed to prevent moisture loss.

[On Travel Pack or Flexible Pack or Mobile Pack or Belt Pack]

Peel back label slowly. Pull out wipes as needed and reseal label. Unfold wipe.

[On Packet]

Tear open packet. Unfold wipe.

**\*PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

\*CAUTION: Avoid contact with eyes.

\*Do not use for cleansing or sanitizing human skin.

**\*FIRST AID**

\*If in eyes: Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

\*STORAGE AND DISPOSAL: Wipe: Do not reuse wipe. Dispose of used wipe in trash collection. Do not flush. Wrap empty [container] [travel pack or flexible pack or mobile pack or belt pack] in paper, then discard in trash. [Omit previous sentence for single packets.] Do not use or store near heat or open flame. Use product only from original container.

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7/8

[Optional non-food contact section. If nonfood contact use is on label, all required elements in this nonfood contact section must appear on product label under directions for use, after food contact surface items. The asterisks specify passages required if the optional section is used.]

### \*[NON-FOOD CONTACT SURFACES]

\*[Cleaning and] Sanitizing Procedure: Use wipe to sanitize surface. For heavily soiled items, clean prior to sanitizing. Wipe enough for treated surfaces to remain visibly wet for 5 minutes. Use additional wipes as needed to keep entire surface area wet for a full 5 minutes. Let air dry. No rinsing required.

\*[Use one or more of the following: [Dining tables,] [chairs,] [infant high chairs,] [booster seats,] [floors,] [sinks,] [faucets,] [toilet seats and rims,] [vanities,] [towel dispensers,] [railings,] [infant-changing tables,] [stall doors,] [bath tubs,] [showers,] [hampers,] [tiled walls,] [telephones,] [shopping carts,] [cash registers,] [(store) check-out areas,] [playpens,] [cribs,] [diaper pails] [and] [doorknobs,]

99.9% effective in 5 minutes against *Staphylococcus aureus* (ATCC 6538) *Salmonella choleraesuis* (ATCC# 10708), and *Klebsiella pneumoniae* (ATCC#4352) [in the presence of organic soil (5% blood serum)].

[All below are optional label (placement optional) literature and promotional statements]

[Pre-measured, pre-moistened sanitizing wipes for use on precleaned food contact surfaces.]

[Aids in the reduction of cross contamination between treated surfaces.]

[Antibacterial]

[Antimicrobial]

[Kills common household bacteria]

[Kitchen surface wipes]

[Cleans, deodorizes and kills common household bacteria]

[No mixing or measuring required]

[Sanitizes hard nonporous surfaces]

[For use on precleaned [and rinsed] food contact surfaces]

[Eliminates odors]

[Kills common household bacteria such as [*Staphylococcus aureus*] [(Staph)]]

[The fast, easy and effective way to sanitize precleaned, hard nonporous surfaces.]

[For use on hard nonporous surfaces in kitchens [and restrooms].]

[Kills 99.999% of *Staphylococcus aureus* (ATCC #6538), *Escherichia coli* (ATCC#11229), *Shigella boydii* (ATCC#9207)]

in 60 seconds on precleaned [and rinsed] food contact surfaces.]

[One-step no rinse sanitizer for nonfood contact surfaces.]

[Use to sanitize meat thermometers.]

[Use to sanitize food thermometers.]

[Use to sanitize food and meat thermometers.]

[The bacteria are killed by 60 seconds in contact with the liquid in the wipe. The product is most effective when the surface is completely contacted with the wipe.]

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Lists of items can be used partially or in their entirety

[The following graphics and statements are optional.  
They may be placed anywhere on label/container.]



[This graphic shows use of the wipe dispenser.]



**NOT A BABY WIPE**

**NOT FOR USE ON SKIN**

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g:\del\p\p\label-wipe label-final 022603.doc Page 5 of 5 3/26/03