

9480-7

3-26-2004

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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 26 2004

Term of Issuance:

Conditional

Name of Pesticide Product:

SANI-WIPE

NOTICE OF PESTICIDE:

 Registration
 Re-registration

(under FIFRA, as amended)

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)(5) providing:

You must 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.

On page 5/6 of the label you must delete the word "sanitizer" in the non-food use site listing called "sanitizer sinks", and submit, prior to using this revised label, three color copies of a final printed production label which reflects this change.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA Section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

Signature of Approving Official:

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

Date:

MAR 26 2004

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Page 2: EPA Reg. No. 9480-7

A copy of the "Master Label" stamped "Accepted" is enclosed with the word "sanitizer" deleted from page 5/6 as mentioned above. This label supercedes all prior labels.

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

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[FRONT PANEL]

*SANI-WIPE®

*NO RINSE HARD, NON-POROUS SURFACE SANITIZING WIPE

[FOOD CONTACT SURFACES]

[Designed for sanitizing cleaned hard, non-porous food contact surfaces where the control of cross contamination between treated surfaces is of primary importance]

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

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

[Premeasured, premoistened sanitizing wipes for use on hard non-porous surfaces.]

*ACTIVE INGREDIENTS

*n-Alkyl(C ₁₂ ,67%, C ₁₄ ,25%, C ₁₆ ,7%, C ₈ , C ₁₀ , C ₁₈ ,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]

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

*Two Nice-Pak Park

*Orangeburg, NY 10962-1376 [for use supplemental distributor name/address if appropriate]

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

ACCEPTED
with COMMENTS
in EPA Letter Dated

MAR 2 5 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.

9480-7

THE INFORMATION IN BOX IS 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 155.10.
 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 except for the
 product primary brand name which can be only changed by notification or amendment. Lists 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,
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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 cleaned hard, non-porous food contact surfaces in kitchens.]

[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]

ACCEPTED
with COMMENTS
in EPA Letter Data A

MAR 26 2004

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***DIRECTIONS FOR USE:**

*It is violation of Federal law to use this product in a manner inconsistent with its labeling.
[Product is ready for use, no mixing or measuring required.]

***FOOD CONTACT SURFACES**

For use on cleaned [or thoroughly washed] then rinsed hard non-porous food preparation surfaces. Surfaces may include: [Use one or more of the following:] [tables,] [food preparation tables,] [counter tops] [non-wood cutting boards,] [probe portion of meat thermometers,] [probe portion of food thermometers,] [take out counters,] [cafeteria trays,] [bar tops,] [waitress stations,] [food carts] [and] [microwaves,] [ranges,] [reach-in refrigeration and freezer units,] [scales,] [walk-in refrigeration and freezer units,] [work tables,] [self service condiment areas,] [self service service areas] [The following uses must be preceded by the words: "[outside surface(s) of]" or "[exterior surface(s) of]":] [beverage dispensers,] [food mixers,] [ice machines,] [steam tables,] [griddles,] [chargrills,] [broilers,] [cooking surfaces and [backsplashes,] [ovens,] [pulpers,] [Add the following after the list of surfaces:] and other similar hard, non-porous food contact surfaces except for those excluded by this label.

*Cleaning and Sanitizing Procedure: Thoroughly clean all food contact using suitable detergents, brushes, sponges and any other necessary equipment. Then rinse with potable water and sanitize 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 required.

*All applicable health inspection agency code requirements must be followed for cleaning, rinsing and sanitizing.

*+Do not use to sanitize glassware, cookware, eating utensils, and wood cutting boards. Do not use to sanitize food preparation surfaces that are scored or gouged with narrow crevices that cannot be penetrated by wiping. Do not use to sanitize other food contact surfaces which, by their design or configuration, cannot be fully reached or covered by a wet wipe.

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

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Under the Federal Insecticide,
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*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 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] [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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[Optional non-food contact section. If non-food contact use is on label, all required elements in this non-food 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]**

[Thoroughly preclean if surface is visibly soiled.]

*[Cleaning and] Sanitizing Procedure: For heavily soiled items, clean prior to sanitizing. Use wipe to sanitize surface. 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,][display cabinets,] [employee areas,] [garbage cans,][infant high chairs,] [booster seats,] [floors,] [sinks,] [sinks,] [drain boards,] [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]

[Recommended for use on hard, non-porous non-food contact surfaces as a one step sanitizer.]

[Premeasured, premoistened sanitizing wipes for use on cleaned hard, non-porous 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 non-porous surfaces]

[For use on cleaned [and rinsed] hard, non-porous food contact surfaces]

[Eliminates odors]

[Kills common household bacteria including Staphylococcus aureus (Staph)]

[The fast, easy and effective way to sanitize cleaned, hard non-porous surfaces.]

[For use on hard non-porous surfaces in kitchens [and restrooms].]

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

[in 60 seconds on cleaned [and rinsed] hard, non-porous food contact surfaces.]

[One-step no rinse sanitizer for hard, non-porous non-food contact surfaces.]

[Use to sanitize the probe portion of meat thermometers.]

[Use to sanitize the probe portion of food thermometers.]

[Use to sanitize the probe portion of food and meat thermometers.]

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

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OPTIONAL GRAPHICS

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



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9480-17

[This graphic shows use of the wipe dispenser.]

NOT A BABY WIPE

NOT FOR USE ON SKIN

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