

9480-7

7-3-2002

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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:

JUL 03 2002

NOTICE OF PESTICIDE:

Registration
 Re-registration

(under FIFRA, as amended)

Term of Issuance:

This Notice of Registration expires on 7/1/03 and supercedes the Registration Notice which expires on July 5, 2002.

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) provided that:

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:

JUL 03 2002

2. You must submit confirmatory data, according to the schedule listed below, using the revised formula which was approved 1/30/02, for each organism intended for **food contact** use sites on the attached accepted 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 for each organism intended for **non-food contact** use sites on the label, using DSS/TSS #10.

A. Submit final reports for the already completed food contact data on glass slides on *S. aureus* and *E. coli*, by 8/1/2002.

B. We accept your request to bridge the *S. aureus* glass and rough plastic food contact data to satisfy the *S. aureus* non-food contact data. The basis of our decision is that the food contact towelette protocol has more stringent performance criteria than the DSS/TSS#10. This bridging acceptance now makes your proposed 2/14/03 and 3/7/03 data completion dates irrelevant. Therefore, except for the two completed glass slide studies referenced above, final report data must be submitted, **in one single comprehensive submission**, for all remaining required studies by 2/1/2003. We suggest you try to accelerate the proposed testing schedule listed in your letter dated 6/13/2002 to allow adequate time for EPA to review all data prior to the registration expiration date on 7/1/2003.

C. Submit an initial simple data summary for each completed batch of organisms intended for food contact use sites as they are completed (eg., submit rough plastic and glass data summaries soon after the proposed completion dates on 9/13/2002 and 10/25/2002). You must still submit final data for these and all remaining required studies as listed in item B above.

3. The submitted data in item #2 above must be found to be acceptable in order for EPA to change the "Terms of Issuance" of this registration. If any of the submitted data are not found to be acceptable, this registration will automatically expire on 7/1/2003.

4. You must make the following changes to the "Master Label" and submit two copies of final printed labels by 9/1/2002. All marketplace versions of this label must use the normal required pesticide label elements and can only use the claims and statements listed on this label. Pictures, symbols, diagrams, representations, logos, etc. which are not on this label version must be submitted and approved by notification, and possibly by amendment. Note that we do not stamp notification labels. This label supercedes all prior stamped labels.

A. Globally delete the unqualified "germs" claim from the label and replace with "bacteria".

B. Globally change all 30 second contact times to "60 seconds" or "one minute".

C. On the back panel, you must designate all listed use sites as required label elements using an asterisk (*). Various label versions can delete one or more use sites, but all relevant use sites must be listed on all label versions.


D. In both the food and non-food use directions, change "Use wipe to sanitize surface" to "Use first wipe to pre-clean and remove heavy soil. Use second wipe to sanitize".

The cutting board submitted in June 2002 to represent a rough plastic surface is acceptable. Note that due to the affinity/binding nature of quats to towlette material, any change in towlette composition requires submission of confirmatory data for food and non-food claims.

A copy of the "Master Label", stamped "accepted with comments", is attached for your records. This is an identical label version as stamped on 3/14/2002.

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

***ACTIVE INGREDIENTS**

n-alkyl(C₁₂67%,C₁₄25%,C₁₆7%,C₈,C₁₀,C₁₈,1%)Dimethyl Benzyl
Ammonium Chloride..... 0.0175%

Isopropyl Alcohol..... 5.4800%

INERT INGREDIENTS:.....94.5025%

TOTAL.....100%

***KEEP OUT OF REACH OF CHILDREN**

***CAUTION**

See back panel for additional precautionary statements

**ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUL 03 2002**

***NET WT.**

NET CONTENTS #OF CLOTHS SIZE

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

E.P.A. Est No.9480-NY-001

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

Two Nice-Pak Park

Orangeburg, NY 10962-1376

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

9480-7

*** MUST APPEAR ON LABEL -(THIS STATEMENT NOT PART OF LABEL COPY)**

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MASTER LABEL COPY FRONT PANEL

SANI-WIPE™

*NO RINSE HARD NON-POROUS SURFACE SANITIZING WIPE

*Especially designed for use on hard, non-porous food contact surfaces where the control of cross contamination is of prime importance.

*99.999 % effective in 30 seconds against Staphylococcus aureus (ATCC #6538), Escherichia coli (ATCC#11229) Listeria monocytogenes (ATCC#19115), Shigella boydii (ATCC#9207) on food contact surfaces.

Pre-measured, pre-moistened sanitizing wipes for use on hard non-porous surfaces.

Aids in the reduction of cross contamination.

No mixing or measuring required.

For use in food service, restaurants and food processing areas.

For use in food service in healthcare settings.

Antibacterial

Antimicrobial

Kills common household germs and bacteria

Kitchen surface wipes

Cleans, deodorizes and kills common household germs

No mixing, no measuring required

Sanitizes hard non-porous surfaces

For use on food contact surfaces

Kills 99.999% of Staphylococcus aureus (ATCC #6538), Escherichia coli (ATCC#11229) Listeria monocytogenes (ATCC#19115), Shigella boydii (ATCC#9207) in 30 seconds on food contact surfaces.

Eliminates odors

Kills common household germs such as Staphylococcus aureus (Staph).

The easy and effective way to sanitize hard non-porous surfaces against common household germs.

For use on hard non-porous surfaces in household kitchens and bathrooms.

* MUST APPEAR ON LABEL - THIS STATEMENT NOT PART OF LABEL COPY

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9480-7

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

*Cleaning and Sanitizing Procedure: Use wipe to sanitize surface. Wipe enough for treated surfaces to remain visibly wet for 30 seconds. Let air dry. No rinsing required.

***NON FOOD CONTACT SURFACES**

Bathroom sinks, faucets, toilet seats and rims, vanities, towel dispensers, railings, infant-changing tables, stall doors, bath tubs, showers, hampers and tiled walls, telephones, playpens, cribs, diaper pails and doorknobs.

*99.9% effective in 5.0 minutes against Staphylococcus aureus (ATCC 6538) Salmonella choleraesuis (ATCC#10708), and Klebsiella pneumoniae (ATCC#4352).

*Cleaning and Sanitizing Procedure: Use wipe to sanitize surface. Wipe enough for treated surfaces to remain visibly wet for 5 minutes. If needed use additional wipes to keep surface area wet for a full 5 minutes. Let air dry. No rinsing required.

*Do not flush

*Dispenser: To start feed: Remove large cover and discard seal from container. From center of toweled roll, pull up wipe corner, twist into a point and thread through the hole in the container cover. Pull through about one inch. Replace cover. Pull out first wipe and snap off at a 90° angle. Remaining wipes feed automatically ready for next use. When through using, keeps small center cap closed to prevent moisture loss.

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

Do not use for cleaning or sanitizing human skin. Do not use as a diaper wipe or for personal cleansing.

*CAUTION: Avoid contact with eyes. In case of eye contact, flush with plenty of water for at least 15 minutes. If irritation persists, call a physician.

*STORAGE AND DISPOSAL: Wipe: Do not reuse wipe. Dispose of used wipe in trash collection. Do not use or store near heat or open flame. Use product only in original container.

* MUST APPEAR ON LABEL -(THIS STATEMENT NOT PART OF LABEL COPY)
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JUL 03 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the pesticide. 9490-17

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BACK PANEL

AREAS OF USE IN FOOD SERVICE AND FOOD PREPARATION :

This product is recommended for use in restaurants, food processing plants, supermarkets, hotels, kitchens, airlines, food service in healthcare settings and food service and food preparation settings where the control of the hazards of cross contamination is of primary importance.

Recommended for use on hard non-porous surfaces in household kitchens and bathrooms.

FOR USE IN:

Restaurants
Food Processing Plants
Cafeterias
Hotels, Motels
Nursing Homes
Schools
Camp Sites, RV's

Fast Food Chains/Delicatessens
Poultry/Meat Packing Facilities
Airplanes
Day Care Settings
Healthcare Settings
Nurseries

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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. Pre-clean if surface is visibly soiled.

*FOR USE ON

Hard non-porous surfaces and equipment.

*FOOD PREPARATION/FOOD CONTACT SURFACES

Counter tops, sinks, drain boards, faucets, cabinets, stoves, hoods, non-wood cutting boards, refrigerators, food cases, microwaves, floors, appliances, tables chairs, infant high chairs, and booster seats.

99.999 % effective in 30 seconds against Staphylococcus aureus (ATCC #6538), Escherichia coli (ATCC#11229) Listeria monocytogenes (ATCC#19115), Shigella boydii (ATCC#9207) on food contact surfaces.

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

* MUST APPEAR ON LABEL -(THIS STATEMENT NOT PART OF LABEL COPY)

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