

9480-7

3-1-2005

1/12

MAR 01 2005

Christina Griffin
Agent for PDI, The Healthcare Division of Nice-Pak Products, Inc.
c/o Delta Analytical Corporation
7910 Woodmont Avenue, Suite 1000
Bethesda, MD 20814

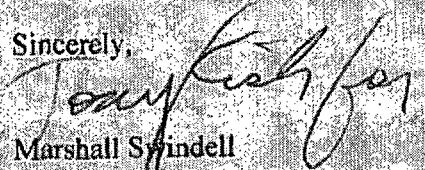
Subject: Sani-Wipe
EPA Reg. No. 9480-7
Notification Dated 9/22/04, Received 2/23/05

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to provide a revised label which adds the NSF logo, and shopping cart graphics on page 6/7, is acceptable.

As per the guidance on the EPA website, the NSF logo should not be placed on the front panel, and it appears that the label statement above the NSF logo "OPTIONAL [For side or back panel only]", complies with Agency guidance.

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 I
Antimicrobial Division (7510C)

2/23



Fax

DATE: *2/23/05*
 PAGES: *12*



TO: *Tony Kish*
 COMPANY:
 VOICE NUMBER:
 FAX NUMBER:

NOTE:

Notification we discussed. See e-mail next page. Only page 7 of label was changed, no other changes. Please respond ASAP.

Thank you.



FROM *Cristine Griffin*

(301) 652-5495 VOICE NUMBER
(301) 652-5408 FAX NUMBER

3/18

Cristina Griffin

From: Kish.Tony@epamail.epa.gov
 Sent: Wednesday, February 09, 2005 1:09 PM
 To: Cristina Griffin
 Cc: 'David Jones'; negron.juan@epamail.epa.gov; Swindell.Marshall@epamail.epa.gov
 Subject: 2/23/05 Re: Summary of EPA/PDI meeting of 1/26/05



Summary of PDI meeting with EP

Tony - I spoke with Marshall & he said it was fine to fax the notification to you. This is a very simple notification. Please respond ASAP. Cristina Griffin

The 12-13-04 notification is not in our receipts tracking. Contact Marshall and if OK with him, fax it in to 703-308-8481. No other comments. Tony

Cristina Griffin
 <cgriffin@delta-ac.com>

02/03/2005 08:14 AM

TO: Tony Kish/DC/USEPA/US@EPA, Juan Negron/DC/USEPA/US@EPA

CC: "'David Jones'" <djones@nicepak.com>

SUBJECT: Summary of EPA/PDI meeting of 1/26/05

Tony and Juan,

Here is the summary of our meeting last week, and subsequent follow up conversations. Please let me know if you have any comments. Again, thank you for your help.

Tony, one question I still have is with regards to the notification on 9480-7. Please check your records. We resubmitted it 12/13/04 and still haven't heard anything. It was a simple label notification to add graphics and minor wording.

Best Regards,
 Cristina Griffin
 Delta Analytical Corp.
 e-mail: cgriffin@delta-ac.com
 voice: 301-652-5495

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Apparently this
was not received
so we are resubmitting
~~September 22, 2004~~
December 14, 2004



Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave. NW
Washington DC 20460

Attn: Marshall Swindell, PM 33

RE: Notification to add NSF logo and shopping cart graphics to the label
Product: Sani-Wipe, EPA Reg. No. 9480-7
Company: PDI, The Healthcare Division of Nice-Pak Products, Inc.

Dear Marshall:

On behalf of PDI, The Healthcare Division of Nice-Pak Products, Inc., I am submitting a notification to add the NSF logo and shopping cart graphics to the label for the product Sani-Wipe, EPA Reg. No. 9480-7. NSF logo is consistent with the EPA letter to NSF dated 7/28/04. The only change to this label is the addition of page 7; no text or other graphics have been changed.

Enclosures

- EPA form 8570-1
- Copy of label; only page 7 is added (see sticky note indicating revised page)

If you have any questions regarding this submission, please contact me at 301-652-5495 or cgriffin@delta-ac.com.

Sincerely,

Debbie Dawson for

Cristina Griffin
Agent for PDI

Enclosures

cc: David Jones, PDI

Page 3 of 12

5/12



September 22, 2004

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Sincerely,

Debbie Dawson for

Cristina Griffin
Agent for PDI

Enclosures

cc: David Jones, PDI

6/12

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0050.



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
295762

Application for Pesticide - Section I

1. Company/Product Number 9480-7	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) PDI, Healthcare Division of Nice-Pak Products, Inc./ Sani-Wipe	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) PDI, Health Care Div. of Nice-Pak c/o Delta Analytical Corp. 7910 Woodmont Ave. Suite 1000 Bethesda MD 20814 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

Amendment - Explain below
 Resubmission in response to Agency letter dated _____
 Notification - Explain below.

Final printed labels in response to Agency letter dated _____
 "Mu Too" Application.
 Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Notification to add NSF logo and shopping cart graphics to the label.
 This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10, and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material this Product will be Packaged in:

Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted.		If "Yes," Unit Package wgt. No. per container	If "Yes," Unit Package wgt. No. per container

3. Location of Net Contents Information
 Label Container

4. Size(s) of Retail Container

5. Location of Label Direction
 On Label
 On Labeling accompanying product

6. Manner in Which Label is Affixed to Product
 Lithograph Other _____
 Paper glued
 Stenciled

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Cristina Griffin	Title Agent for PDI	Telephone No. (Include Area Code) 301-652-5495
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Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any kind of knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature <i>Debbie Davison for</i>	3. Title Agent for PDI	8. Date Application Received (Stamped)
4. Typed Name Cristina Griffin	5. Date September 22, 2004	

50F12

[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 ₁₂ ,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 *[or use supplemental distributor name/address if appropriate]*

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

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 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 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, partial deletion, merging, or similar.

[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]

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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 serviceware 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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*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 rescal 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,] [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.]

[Pre-measured, 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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12/12

OPTIONAL GRAPHICS

[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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