

9480-7

3/4/2014

1/12



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Cristina Griffin
Agent for Professional Disposables International, Inc. (PDI)
c/o Delta Analytical Corporation
Silver Spring, MD 20904

MAR 4 2014

Subject: Notification; Per PR-Notice 98-10
Product Name: Sani-Wipe
EPA Registration Number: 9480-7
Application Date: October 29, 2013

Dear Ms. Griffin:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 dated September 10, 2013 for the product referenced above. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10. The addition of the new Alternate Brand Names (ABN) and graphics are acceptable, and will be placed in our records.

If you have any questions regarding this letter, please email Amaris Johnson at johnson.amaris@epa.gov or call (703) 305-9542.

Sincerely,

A handwritten signature in black ink that reads "Amaris Johnson for".

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division (7510P)
Office of Pesticide Programs

Please read instructions on reverse before completing form.

Form Approved. Gov. No. 2070-0060.



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
NOTIF

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) Professional Disposables International, Inc. (PDI) / Sani-Wipe	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Professional Disposables International, Inc. (PDI) c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904 <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 _____
 "Me Too" Application.
 Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
Notification per PR Notice 98-10 to add Alternate Brand Names and graphics .
 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 Professional Disposables International, Inc. (PDI)	Telephone No. (include Area Code) 301-680-7971
---------------------------------	--	--

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 	3. Title Agent for Professional Disposables International, Inc. (PDI)	6. Date Application Received (Stamped)
4. Typed Name Cristina Griffin	5. Date October 29, 2013	

5/12



October 29, 2013

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive, Room S-4900
Arlington VA 22202

Attn: Marshall Swindell, PM 33

RE: Notification per PR Notice 98-10 to add Alternate Brand Names and graphics
Product: Sani-Wipe, EPA Reg. No.: 9480-7
Company: Professional Disposables International, Inc. (PDI)

Dear Marshall:

On behalf of Professional Disposables International, Inc. (PDI), I am submitting a label notification per PR Notice 98-10 to add Alternate Brand Names and graphics for Sani-Wipe, EPA Reg. No. 9480-7. The new Alternate Brand Names are on page 1, and the new graphics are on page 9. All additions to the label are highlighted. Please note that with the addition of the new Alternate Brand Names we moved claims language from page 1 to page 6. This is all EPA approved language that we needed to move to make room on page 1.

The new Alternate Brand Names are:

- Sani-Professional® Brand Thermo-San® Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand Thermo-San® No-Rinse Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand Thermo-San® No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand FC-7® Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand FC-7® No-Rinse Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand FC-7® No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand No-Rinse Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes
- PDI® Thermo-San® Food Contact Surface Sanitizing Wipes
- PDI® Thermo-San® No-Rinse Food Contact Surface Sanitizing Wipes
- PDI® Thermo-San® No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes
- PDI® FC-7® Food Contact Surface Sanitizing Wipes
- PDI® FC-7® No-Rinse Food Contact Surface Sanitizing Wipes
- PDI® FC-7® No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes
- PDI® Food Contact Surface Sanitizing Wipes
- PDI® No-Rinse Food Contact Surface Sanitizing Wipes
- PDI® No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes

The following documents are enclosed in support of this notification:

- EPA form 8570-1
- One copy of the revised label (changes are highlighted)

If you have questions, please contact me at 301-680-7971 or cgriffin@delta-ac.com.

Sincerely,

Cristina Griffin
Agent for Professional Disposables International, Inc. (PDI)

Enclosures

cc: Elizabeth Ernst, PDI

4/12

[FRONT PANEL]

***SANI-WIPE®**

***NO RINSE HARD, NON-POROUS SURFACE SANITIZING WIPE**

[Previously approved Alternate Brand Names:]

Sani Professional® Brand Sani-Wipe[s]

Sani Professional® Brand Table Turners™ No-Rinse Sanitizing Wipe[s]

[Adding the following new Alternate Brand Name]

- Sani-Professional® Brand Thermo-San® Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand Thermo-San® No-Rinse Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand Thermo-San® No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand FC-7® Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand FC-7® No-Rinse Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand FC-7® No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand No-Rinse Food Contact Surface Sanitizing Wipes
- Sani-Professional® Brand No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes
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- PDI® No-Rinse Food Contact Surface Sanitizing Wipes
- PDI® No-Rinse, Hard, Non-porous Food Contact Surface Sanitizing Wipes

***ACTIVE INGREDIENTS**

*n-Alkyl(C₁₂67%, C₁₄25%, C₁₆7%, C₈, C₁₀, C₁₈,1%) Dimethyl Benzyl

*Ammonium Chloride..... 0.0175%

*Isopropyl Alcohol..... 5.4800%

*OTHER INGREDIENTS 94.5025%

*TOTAL100.0000%

[Does not include the weight of the [cloth] [towelette] [or] [wipe]]

***KEEP OUT OF REACH OF CHILDREN**

***CAUTION**

*See back [side] panel for additional precautionary statements

*NET CONTENTS [and/or Net Wt.] _____oz (g) [or lbs. (kg)]

* _____# OF CLOTHS [SIZE of each cloth]

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

* EPA Est. No.9480-NY-1 [or EPA Est. No. A=9480-NY-1, B=72956-WI-1, C=72956-AR-1

Alpha character will precede batch number on product container]

[Manufactured by [or for]]:

Professional Disposables International, Inc.

Two Nice-Pak Park, Orangeburg, NY 10962-1376

[For information call: [phone number to be inserted]]

[Made in USA]

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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.

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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.]

[Not for in-home use]

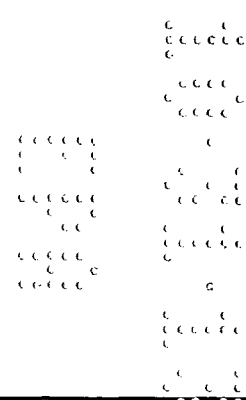
[Not for retail sale]

[Not for sale in (insert state(s))]

[FOR USE IN:]

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

- [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**

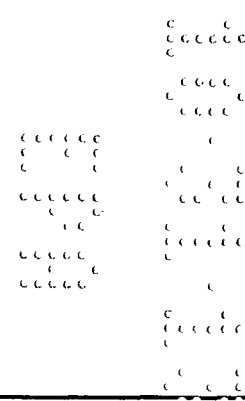
For use on cleaned [or thoroughly washed] then rinsed hard non-porous food preparation surfaces. Surfaces may include: [Use one or more of the following:] [tables,] [food preparation tables,] [counter tops] [non-wood cutting boards,] [probe portion of meat thermometers,] [probe portion of food thermometers,] [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 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**

Do not contaminate water, food, or feed by storage and disposal.

[For canisters:]

Storage: Do not use or store near heat or open flame. Use product *only* from original container. **Wipe**

Disposal: Do not reuse wipe. Dispose of used wipe in trash. Do not flush in toilet. **Dispenser**

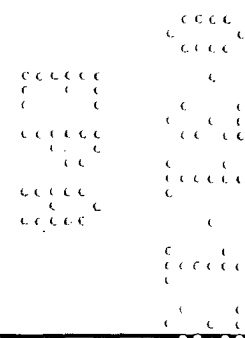
Disposal: Nonrefillable container. Do not reuse or refill this container. Triple rinse and offer for recycling. If recycling is not available, put in trash collection.

[For flexible packs, mobile packs, belt packs or single packets:]

Storage: Do not use or store near heat or open flame. Use product *only* from original container. **Wipe**

Disposal: Do not reuse wipe. Dispose of used wipe in trash. Do not flush in toilet. **Dispenser**

Disposal: Put empty [flexible pack] or [mobile pack] or [belt pack] or [packaging] in trash collection.



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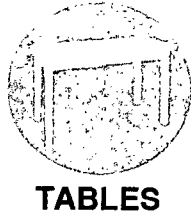
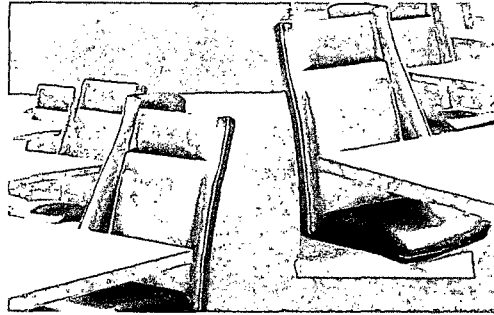
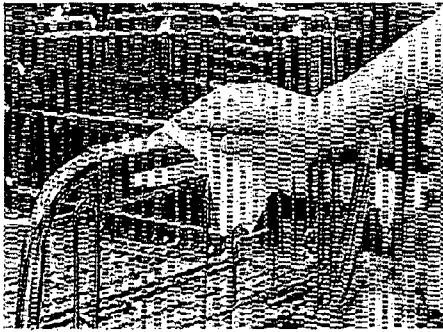
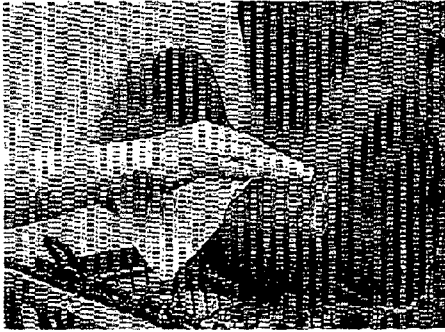
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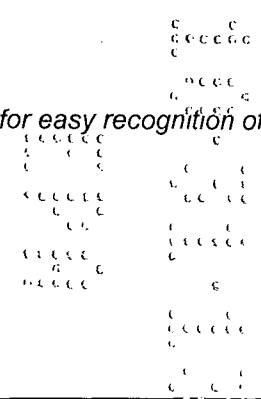
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[The following graphics and statements are optional. They may be placed anywhere on label/container.]



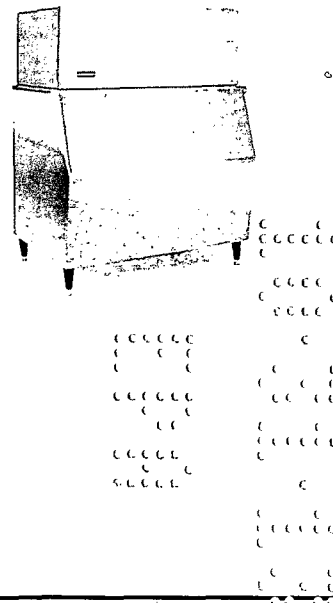
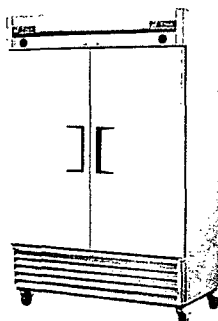
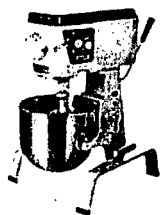
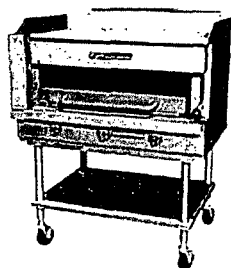
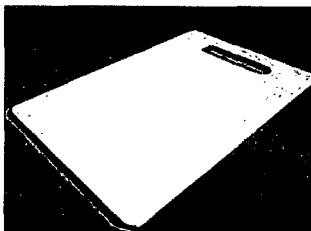
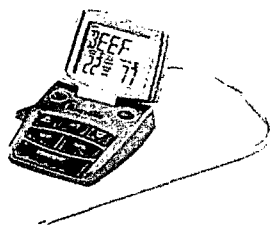
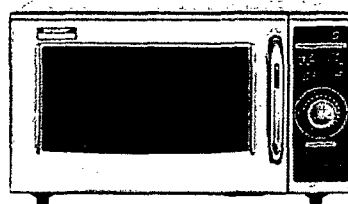
[The following are company logos for use on PDI product labels. The purpose of the logo is for easy recognition of PDI products in the marketplace.]



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[The following graphics and statements are optional.
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THERMO-SAN™

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