

9480-7

10/12/2001

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 12 2001

Christina Griffin, Agent for Professional Disposables, Inc.
c/o Delta Analytical Corporation, Suite 1000,
7910 Woodmont Avenue, MD 20814

Subject: Sani-Cloth Germicidal Wipes
EPA Reg. No. 9480-7
Your Amendment Dated 6/15/2001

The subject amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to provide revised labeling which changes the 60 second food contact time to 30 seconds, and deletes "pre-cleaned" (except for visibly soiled uses) wherever it appears, is acceptable with the conditions listed below:

Conditions

1. The label must be revised as follows: Delete the added "toys" use. We did not allow this use as per our letter dated 8/15/2000 and have not changed our position. We have "blacked-out" this use on the stamped label.

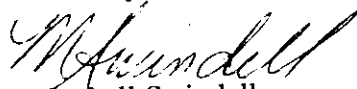
2. As per the original Notice of Registration dated 4/5/2001 for this product, approval of this amendment is time limited and automatically expires on 4/5/2002. Registration extension is subject to satisfying all the original and current conditions of registration.

3. A 30 second label contact time is acceptable because the submitted data meets the 30 second contact time required in the interim protocol. Note that some States may require a 60 second contact time on the label for food contact sanitizers. Deletion of "pre-cleaned" (except for visibly soiled applications) is acceptable because the test data passed as a one step product.

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

If you have any questions about the comments in this letter, please feel free to contact me at 703-308-6341, or Tony Kish at 703-308-9443.

Sincerely,



Marshall Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES

| SYMBOL | SURNAME | DATE |
|--------|---------|------|
| | | |
| | | |
| | | |

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.

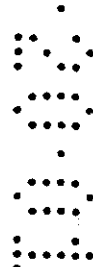
* MUST APPEAR ON LABEL - (THIS STATEMENT NOT PART OF LABEL COPY)
6/4/01 2:06 PM

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 12 2001

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

9480-7



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

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*NET WT.

NET CONTENTS #OF CLOTHS SIZE

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

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

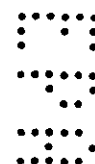
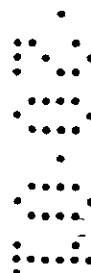
PDI, The Healthcare Division of Nice-Pak Products, Inc.

Two Nice-Pak Park

Orangeburg, NY 10962-1576

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

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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

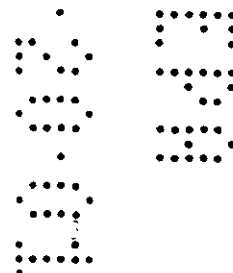
Counter tops, sinks, drain boards, faucets, cabinets, stoves, hoods, non-wood cutting boards, refrigerators, food cases, microwaves, floors, appliances, tables chairs, infant high chairs, and booster seats.

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.

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*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.

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