


PM 33 9480-6

1/6/99

1 of 12

 <p>U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (H7505C) 401 "M" St., S.W. Washington, D.C. 20460</p>	EPA Reg. Number: 9480-6	Date of Issuance: JAN 06 1999
	Term of Issuance: CONDITIONAL	
	Name of Pesticide Product: Sani-Cloth Plus Germicidal Disposable Cloth	

NOTICE OF PESTICIDE:
☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):
**Professional Disposables, Inc.
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 sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
2. Add the phrase EPA Registration Number "EPA Reg. No. "9480-6".

Signature of Approving Official: Marshall Swindell Product Manager 33 Regulatory Management Branch 1 Antimicrobial Division (7510W)	Date: JAN 06 1999
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3. Within 18 months (July 6, 2000) of the date stamped on this Notice, you must submit the following data to EPA and have it approved by EPA:

A. Confirmatory data for *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, and *Staphylococcus aureus* are to be developed on two lots, one of which is 60 days old. The AOAC Germicidal Spray Products Test modified for towelettes is to be employed. The test conditions must be for a 5 minute contact time and a 5% organic load.

B. Validation data for TB must be generated on one sample by a laboratory other than the laboratory used to generate the original data. The AOAC Germicidal Spray Products Test modified for towelettes must be employed. The test conditions must be for a 5 minute contact time and a 5% organic load.

4. You must make the following three label changes and submit two copies of the revised final printed label for the record.

(A) On page one, change "A novel way to effectively disinfect environmental surfaces", to read "An effective way to disinfect hard, nonporous environmental surfaces".

(B) Insert the phrase "Rhinovirus type 13" everywhere the word "Rhinovirus" appears.

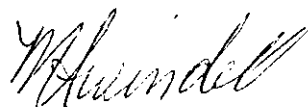
(C) On page nine, change "...Staph and other harmful germs..." to "...Staphylococcus and other harmful germs ...".

This Conditional Registration will expire automatically on July 6, 2000. If you fail to satisfy all the conditions imposed in this registration, EPA may issue a Notice to Cancel under Section 6 (e) of FIFRA. Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Tony Kish at (703) 308-9443.

Sincerely,



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

Enclosure

December 16, 1998

MASTER LABEL COPY
FRONT COPY

SANI-CLOTH PLUS
GERMICIDAL DISPOSABLE CLOTH

For use in: CRITICAL CARE AREAS

Where control of the hazards of cross contamination is of prime importance

Effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*

Exhibits effective virucidal activity on hard nonporous inanimate surfaces; kills Influenza A2/Hong Kong (representative of the common flu virus) and Herpes simplex Type II (causative agent of genital herpes) in 30 seconds

Kills dangerous viruses such as Influenza A2/Hong Kong and Herpes simplex Type II in 30 seconds.

A novel way to effectively disinfect environmental surfaces.

For use on external Ultrasound Transducers only

Aids in the reduction of cross contamination

Convenient Premeasured Premoistened

Kills *Mycobacterium bovis* BCG (Tuberculosis) in 5 minutes at 20°C.

*Kills HIV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in 30 seconds at room temperature (20-25°C) in health care or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1).

*Kills HIV on pre-cleaned ultrasound probes previously soiled with blood/body fluids in 30 seconds at room temperature (20°C -25°C) in health care or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1).

Kills Rhinovirus in 3 minutes

Kills *Escherichia coli* (E. coli) 0157:H7 in 5 minutes

Bactericidal, Tuberculocidal, and Virucidal*

*Kills Canine Distemper and Pseudorabies Virus in 5 minutes

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 06 1999

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

9480-6

ACTIVE INGREDIENTS:

n-Alkyl (68% C12, 32% C14) dimethyl ethylbenzyl ammonium chlorides 0.125%
n-Alkyl (60% C14, 30% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides. .0.125%
Isopropyl Alcohol 14.85%
INERT INGREDIENTS 84.90%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION:

See back panel for additional precautionary statements

NET WT

NET CONTENTS # OF CLOTHS SIZE

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

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 06 1989

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

9480-6

BACK PANEL

A dual chain Quaternary/Alcohol solution impregnated in a wiping cloth

For use on external Ultrasound Transducers only

To disinfect: Pre clean ultrasound gel from external transducer to be disinfected by using a clean wash cloth. Then thoroughly wet the probe with a towelette for 5 minutes.

Assures proper dilution strength and product effectiveness and standardized technique.

Greater quaternary dispersal with no hazard of cross contamination, quick drying

Non-woven disposable cloth

Effective in 5 minutes against Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa

Kills Mycobacterium bovis BCG (Tuberculosis) in 5 minutes at 20°C.

*Kills Influenza A2/Hong Kong and Herpes simplex Type II in 30 seconds

Kills Rhinovirus in 3 minutes

A non woven disposable cloth for use in hospitals and other critical care areas where control of the hazards of cross-contamination is required. Use on surfaces and equipment such as stainless steel, Formica, glass tables, carts, baskets, counters, cabinets, telephones and other hard non-porous surfaces.

SOME AREAS OF USE: Hard surfaces in Surgery, Recovery, Anesthesia, X-Ray Cat. Lab, ER, Orthopedics, New Born Nursery, Respiratory Therapy, Radiology, Central Supply.

"This product is not be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not originally penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection."

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 06 1999

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

94 80-6:

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST
HIV-1 FOR SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS**

PERSONAL PROTECTION: When using the germicidal cloth, wear disposable protective gloves, protective gowns, face masks, or eye coverings as appropriate when handling HIV-1 infected blood or body fluids.

CLEANING PROCEDURE: All blood and other body fluids must be thoroughly cleaned from surface and objects before disinfection by the germicidal cloth. Open, unfold first germicidal cloth to remove gross filth.

CONTACT TIME: Use second germicidal cloth to thoroughly wet surface. Allow to remain wet 30 seconds, let air dry. Although efficacy at a 30 second contact time has been shown to be adequate against HIV-1 (AIDS VIRUS) this time would not be sufficient for other organisms. Use listed disinfection times against all of the organisms claimed.

DISPOSAL OF INFECTIOUS MATERIALS: Dispose of used towelette in accordance with local regulations for infectious waste disposal.

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 06 1999

Under the Federal Insecticide,
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9480-6

TOWELETTE:

Use a wipe to remove gross filth. Open, unfold, second wipe to thoroughly wet surface. Allow to remain wet 5 minutes, let air dry.

TRAVEL PACK

Peel back label slowly. Pull out wipes as needed and reseal label. Use a wipe to remove gross filth. Open, unfold, second wipe to thoroughly wet surface. Allow to remain wet 5 minutes, let air dry.

DISPENSER:

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

Open, unfold, wipe to remove gross filth. Use second wipe to thoroughly wet surface. Allow to remain wet for 5 minutes, where required let air dry.

PRECAUTIONARY STATEMENTS: Hazards to humans and domestic animals.

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: Towellette: Do not reuse towel. Dispose of used towel in trash.
Dispenser: Do not reuse empty container. Wrap container and put in trash collection.

DO NOT USE OR STORE NEAR HEAT OR OPEN FLAME.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 06 1990

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

9480-6

BACK PANEL

DIRECTIONS FOR USE: TO DISINFECT FOOD CONTACT SURFACES

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

TOWELETTE:

Use wipe to remove gross filth. Open, unfold, second wipe to thoroughly wet surface. Allow to remain wet 5 minutes, let air dry followed by a thorough potable water rinse.

TRAVEL PACK

Peel back label slowly. Pull out wipes as needed and reseal label. Use wipe to remove gross filth. Open, unfold, second wipe to thoroughly wet surface. Allow to remain wet 5 minutes, let air dry followed by a thorough potable water rinse.

DISPENSER:

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

- Open, unfold, wipe to remove gross filth. Use second wipe to thoroughly wet surface. Allow to remain wet for 5 minutes where required, let air dry followed by a thorough potable water rinse.

ACCEPTED
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in EPA Letter Dated:

JAN 06 1999

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

9480-6

DIRECTIONS FOR USE: TO DISINFECT NON - FOOD CONTACT SURFACES

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

TOWELETTE:

Use a wipe to remove gross filth. Open, unfold, second wipe to thoroughly wet surface. Allow to remain wet 5 minutes, let air dry.

TRAVEL PACK

Peel back label slowly. Pull out wipes as needed and reseal label. Use wipe to remove gross filth. Open, unfold, second wipe to thoroughly wet surface. Allow to remain wet 5 minutes, let air dry.

DISPENSER:

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

Open, unfold, wipe to remove gross filth. Use second wipe to thoroughly wet surface. Allow to remain wet for 5 minutes where required, let air dry.

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CONSUMER LABEL

Antibacterial
 Antimicrobial
 Kills Many Germs
 Bath and Kitchen wipes for hard, non-porous surfaces
 Cleans and disinfects
 Kills many bacteria and viruses
 Cleans, deodorizes, and kills common household germs
 No mixing
 Multi purpose cleaner
 Disinfects hard non-porous environmental surfaces

Kills common household germs such as *Staphylococcus aureus* (Staph) and *Salmonella choleraesuis*. Also effective against cold and flu viruses such as Influenza A2/HK (Hong Kong flu).

An effective way to clean, deodorize and sanitize against odor-causing organisms and disinfect hard, non-porous surfaces.

Aids in reducing cross-contamination.

A dual chain Quaternary/Alcohol solution impregnated in a wiping cloth

Assures proper dilution strength and product effectiveness and standardized technique.
 Greater quaternary dispersal with no hazard of cross contamination, quick drying.

Non-woven disposable cloth

Effective in 5 minutes against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*

Kills *Mycobacterium bovis* BCG (Tuberculosis) in 5 minutes at 20° C

Kills Influenza A2/Hong Kong and Herpes simplex Type II in 30 seconds

Kills Rhinovirus in 3 minutes

Kills *Escherichia coli* (E. coli) 0157:H7 in 5 minutes

ACCEPTED
 with COMMENTS
 in EPA Letter Dated:

JAN 06 1993

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

9480-6

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS VIRUS) FOR SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS

PERSONAL PROTECTION: When using the germicidal cloth, wear disposable protective gloves, protective gowns, face masks, or eye coverings as appropriate when handling HIV-1 infected blood or body fluids.

CLEANING PROCEDURE: All blood and other body fluids must be thoroughly cleaned from surface and objects before disinfection by the germicidal cloth. Open, unfold first germicidal cloth to remove gross filth.

CONTACT TIME: Use second germicidal cloth to thoroughly wet surface. Allow to remain wet 30 seconds, let air dry. Although efficacy at a 30 second contact time has been shown to be adequate against HIV-1 (AIDS VIRUS) this time would not be sufficient for other organisms. Use listed disinfection times against all of the organisms claimed.

DISPOSAL OF INFECTIOUS MATERIALS: Dispose of used towelette in accordance with local regulations for infectious waste disposal.

Use on hard non porous surfaces only. Test wipe on small inconspicuous area first

Some areas of use:

Kitchen**: Counter tops, appliances, sinks, faucets, cutting boards

Bathroom: Toilet seats, bathroom fixtures, vanity tops, shower stalls, bathtubs, tiles, sinks

General use: Doorknobs, telephones, laundry rooms, garbage cans, pet areas and more

**A potable water rinse is required for surfaces in direct contact with food.

Use wipes to kill Influenza A2/Hong Kong, Rhinovirus, Salmonella, Staph and other harmful germs on most bath and kitchen surfaces

Do not flush in toilet

ACCEPTED
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in EPA Letter Dated:

JAN 06 1999

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Fungicide, and Rodenticide Act as
amended, for the pesticide,
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9480-6

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

To Clean, Sanitize and Deodorize hard nonporous nonfood contact surfaces.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

TOWELETTE:

Open, unfold, towelette.

Use a towelette to clean heavily soiled surfaces. Use second towelette to disinfect surface. Thoroughly wet surface, allow to remain wet for 5 minutes, let air dry.

TRAVEL PACK

Peel back label slowly. Pull out wipes as needed and reseal label. Use a wipe to clean heavily soiled surfaces. Use second towelette to disinfect surface. Thoroughly wet surface, allow to remain wet for 5 minutes let air dry.

DISPENSER:

To start feed: Remove large cover and discard seal from container. From center of wipe roll, pull up wipe corner, twist it into a point and thread it 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, keep small center cap closed to prevent moisture loss.

Open, unfold, wipe to remove gross filth. Use second wipe to thoroughly wet surface. Allow to remain wet for 5 minutes where required let air dry.

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