GUICE / // // 3/

6-11-2008

Jun 11,08 /15

Ms. Cristina Griffin Agency for Professional Disposables International, Inc. (PDI) c/o Delta Analytical Corp. 12510 Prosperity Drive, Suite 160 Silver Spring, MD 20904

Subject:

Sani-Cloth Plus Germicidal Disposable Cloth

EPA Registration Number 9480-6 Letter Dated February 28, 2008 EPA received date March 13, 2008

Dear Ms. Griffin:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is acceptable.

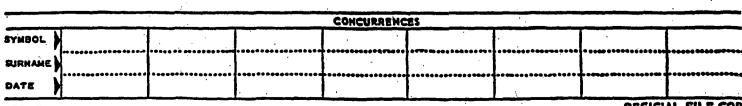
Proposed Amendments:

Revised labeling to reinstate 5 minute claim for (VRE)

General Comments:

The data submitted to support a 5 minute contact time was accepted (in 2005), as it appears on the label stamped August 3, 2005. The data, when reviewed, was considered acceptable for VRE at the 5 minute contact time. The VRE 5 minute contact time is accepted.

A stamped copy of the acceptable labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.



EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OPPICIAL FILE COP

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland at (703) 308-6224 or Velma Noble at 703-308-6233.

Yelina Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7501P)

Enclosure: Label

SANI-CLOTH® PLUS GERMICIDAL DISPOSABLE CLOTH

ACTIVE INGREDIENTS:

KEEP OUT OF REACH OF CHILDREN : CAUTION

See back [side] panel for additional precautionary statements NET CONTENTS

OF CLOTHS [SIZE of each cloth]

EPA Reg. No.: 9480-6

EPA Est. No.: 9480-NY-1

or

EPA Est. No. A=9480-NY-1, B=9480-IN-1

Alpha character will precede batch code on product

ACCEPTED

JUN 11 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pasticide, registered under EPA Reg. No. 9480-

Manufactured by:
Professional Disposables International, Inc.
Two Nice-Pak Park, Orangeburg, NY 10962-1376

Precautionary Statements

Hazards to humans and domestic animals

Caution. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

First aid

If in eves:

Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 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.

Physical or chemical hazard

Combustible. Do not use or store near heat or open flame. Do not use on natural marble, windows, unpainted wood, brass, clear plastic or colored grout.

Bactericidal

Virucidal*

* Herpes Simplex Type 2 (ATCC VR-734), Influenza A2/Hong Kong (ATCC VR-544), Respiratory Syncytial Virus (RSV)

Virucidal against Herpes Simplex Type 2, Influenza A2/Hong Kong, Respiratory Syncytial Virus (RSV), HIV-1[†], Hepatitis B Virus[†], Hepatitis C Virus[†]

Tuberculocidal

[Product name] kills bacteria listed on this label:
Escherichia coli (E. coli) O157:H7 (ATCC 35150)
Escherichia coli (E. coli) (ATCC 11229)
Methicillin Resistant Staphylococcus aureus (MRSA) (ATCC 33592)
Mycobacterium bovis BCG (Tuberculosis) (ATCC 35743)
Pseudomonas aeruginosa (ATCC 15442)
Salmonella enterica (ATCC 10708)
Staphylococcus aureus (ATCC 6538)
Vancomycin Resistant Enterococcus faecalis (VRE) (ATCC 51299)

[Product name] is virucidal against Herpes Simplex Type 2 (ATCC VR-734), Influenza A2/Hong Kong (ATCC VR-544), Respiratory Syncytial Virus (RSV), HIV-1[†], Hepatitis B Virus[†], Hepatitis C Virus[†]

A quaternary/alcohol solution impregnated in a wiping cloth. A non-woven disposable cloth for use in hospitals and other critical care areas where the control of the hazards of cross-contamination between treated surfaces is required. Use on hard non-porous surfaces and equipment listed on this label made of stainless steel, plastic, Formica® and glass. Some organisms are removed from the surface by thoroughly wiping the surface with the wipe. Most remaining organisms are killed within three (3) minutes by exposure to the liquid in the wipe.

♠ 5 minute contact time for TB and VRE, 3 minutes for other listed organisms

Areas of Use:

Hospital and Healthcare Settings: Ambulances, Ambulatory Surgical Centers (ASC), Anesthesia, CAT Labs, CCU, Central Supply, Clinics, Dental Offices, Dialysis Clinics, Doctors Offices, Donation Centers [blood][plasma][semen][milk][apheresis], Emergency Medical Settings, Emergency Rooms, E.R., Emergency Vehicles, Eye Surgical Centers, Healthcare Settings, Health Care Facilities, Home Health Care, Hospices, Hospitals, ICU, Isolation Areas, Laboratory, Laundry rooms, Neonatal Intensive Care Units (NICU), Newborn nursery, Nursing homes, Operating Rooms (OR), Ophthalmic Offices, Orthopedics, Out-Patient Surgical Centers (OPSC), Patient Care Areas, Pediatrics, Pediatric Intensive Care Units (PICU), Physical therapy, Physician's offices, Radiology, Recovery Rooms, Rehabilitation, Respiratory therapy, Surgery, Surgical Centers, Transport vehicles and X-Ray.

Critical Care Areas: CCU, Emergency Rooms, E.R., ICU, Neonatal Intensive Care Units (NICU), Operating Rooms, Pediatric Intensive Care Units (PICU) and Surgery.

Hospital, Healthcare, and Critical Care Use Sites: May be used on hard non-porous surfaces of: ambulance equipment surfaces; bed railings; cabinets; carts; chairs; counters; dental chairs; dental countertops; dental unit instrument trays; endodontic equipment such as apex locators; exam tables; gurneys; infant incubators [interior and exterior surfaces of]; infant warmers [interior and exterior surfaces of]; isolettes; IV poles; laboratory equipment and surfaces; loupes; operating room tables and lights; operatory light switches; oxygen hoods; physical therapy (PT) equipment surfaces; slit lamps; spine back boards; stethoscopes; stretchers; stools; tables; telephones; toilet seats; and hard non-porous outside surfaces of: amalgamators and dental curing lights; anesthesia machines and respiratory therapy equipment; apheresis machines, diagnostic equipment, dialysis machines; patient monitoring equipment, patient support and delivery equipment, pulp testers and motors; toilets; and ultrasound transducers and probes.

Grocery Stores *or* **Shopping Centers** *or* **Supermarkets** *or* **Delicatessens:** Disinfects grocery cart handles and grocery cart child seats. Disinfects shopping cart handles and child seats. Cleans grocery carts *or* shopping carts.

Nursery or Daycare Centers: Bassinets [interior and exterior surfaces of], changing tables, cribs, diaper changing stations, diaper pails, infant/child care equipment surfaces, trash cans, toys and other hard, non-porous surfaces listed on this label.

Bathroom[s] or Public Restrooms: Basins, [bath]tubs, bathroom fixtures, cabinets, countertops, doorknobs, faucet[s], handles, hampers, handrails, shower[s] [stalls], showers, sinks, tiled walls, tiles, toilet [handle] [rim] [seats] [tank] [and other exterior surfaces of], urinals [exterior surfaces of] and vanity tops, and other hard non-porous surfaces listed on this label.

Health club facilities and Gyms: Gym equipment, weight-lifting surfaces and other hard non-porous surfaces listed on this label.

Schools or Classrooms or Office Buildings or Public Facilities or Manufacturing Facilities or Libraries or Public Telephones: Cabinets, chairs, computers, computer monitors, computer mouses, counters, countertops, desks, desktops, doorknobs, fax machines, filing cabinets, filing doors, filing handles, garbage cans, headsets, keyboards, railings, seats, sinks, tables, tabletops, telephones, toys, trash cans, work stations, and other hard non-porous surfaces listed on this label.

Transport vehicles, school busses, public busses, fire trucks, police cars: Hard non porous surfaces of vehicles including steering wheel, hard plastic or metal flooring, seats, and walls.

Restaurants: Hard non porous, non food contact surfaces only including chairs, display cabinets, garbage cans, booster seats, floor, sinks, bathroom surfaces, tiled walls, telephones, cash registers, and doorknobs.

This product is not to 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 ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

Directions for use

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

Dispenser directions:

Canister directions:

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.

Travel pack directions:

Peel back label slowly. Pull out wipes as needed and reseal label. Unfold wipe.

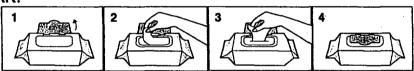
Box directions:

Open along perforations as indicated. Remove packets as needed.

Packet.

Tear open packet. Unfold wipe and use as directed. Discard after single use.

SOLO® PAK:



DO NOT FLUSH • STORE AT ROOM TEMPERATURE DISPOSE OF USED WIPES IN TRASH RECEPTACLE • KEEP SOLO® LID CLOSED WHEN NOT IN USE

REFILL PACKET

This refill package is made for use only in a [product name] canister; do not use this product in a canister for another product. Do not use the refill wipes in a container that is cracked or broken. Discard the cracked or broken container in accordance with the container disposal instructions on the label.

[Option 1]

Remove [entire] lid from canister. Tear open refill [package] at [notch] [mark] [arrow] and place [wipe] roll in empty canister. Follow directions on canister to dispense wipes.

[Option 2]

Remove [entire] lid from canister. Tear open refill [package] at [notch] [mark] [arrow]. Place [entire] refill package of wipes in empty canister. Follow directions on canister to dispense wipes.

GENERIC:

Open lid. Pull out wipe. Close lid tightly.

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

DEODORIZING AND DISINFECTING: To disinfect nonfood contact surfaces only:

Use a wipe to remove heavy soil. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for a full three (3) minutes. Use additional wipe(s) if needed to assure continuous three (3) minute wet contact time. Let air dry. [When TB and/or VRE is included on the label, add the following:] These directions also apply to Mycobacterium bovis BCG (Tuberculosis) at a five (5) minute contact time at 68°F (20°C), and to Vancomycin Resistant Enterococcus faecalis (VRE) at a five (5) minute contact time.

[optional directions:] Ultrasound transducers and probes:

For use on external surfaces of ultrasound transducers and probes only.

To disinfect: Pre-clean gel from external surface of ultrasound transducer or probe to be disinfected by using a clean washcloth. Then thoroughly wet the probe with a towelette. Treated surface must remain visibly wet for a full three (3) minutes. Use additional wipe(s) if needed to assure continuous three (3) minute wet contact time. Let air dry. [When TB and/or VRE is included on the label, add the following:] These directions also apply to Mycobacterium bovis BCG (Tuberculosis) at a five (5) minute contact time at 68°F (20°C); and to Vancomycin Resistant Enterococcus faecalis (VRE) at a five (5) minute contact time.

TKILLS HIV-1 (AIDS VIRUS), HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) ON THE PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS AND PRE-CLEANED EXTERNAL SURFACES OF ULTRASOUND TRANSDUCERS AND PROBES PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in two (2) minutes at room temperature (68°-77°F) or (20°-25°C) in healthcare 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 1 (HIV-1) (associated with AIDS), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV).

[†]SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS

Personal protection: When using this product, wear disposable protective gloves, protective gowns, face masks, or eye coverings as appropriate when handling HIV-1 (AIDS Virus), HBV or HCV infected blood or body fluids.

Cleaning procedure: All blood and other body fluids must be thoroughly cleaned from surfaces and objects before disinfection by the germicidal wipe. Open, unfold first germicidal cloth to remove heavy soil. Disposal of infections materials: Dispose of used towelette in accordance with local regulations for infectious waste disposal.

Contact time: Use second germicidal cloth to thoroughly wet surface. Allow to remain wet two (2) minutes, let air dry. Although efficacy at a two (2) minute contact time has been shown to be adequate against HIV-1, HBV and HCV this time is not sufficient for the other organisms listed on this label. Therefore a three (3) minute wet contact time must be used for other listed organisms. [When TB and/or VRE is included on the label, add the following:], five (5) minutes for TB and VRE.

[Use storage/disposal statement A if canister directions used. Use storage/disposal statement B if travel pack or packet directions used.]

Storage and disposal

Statement A: For canisters and refill dispensers:

Storage: Do not store near heat or open flame. When not in use keep center cap of lid closed to prevent moisture loss.

Towelette Disposal: Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.

Dispenser Disposal: Do not reuse empty container. Triple rinse and offer for recycling. If recycling is not available, put in trash collection.

[If refillable container is being used, substitute the following: Refill Dispenser Disposal: Triple rinse cracked or broken containers and offer for recycling. If recycling is not available, discard in trash.]

Statement B: For packets, travel packs, and [refill] packets:

Storage: Do not store near heat or open flame.

Towelette Disposal: Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet. Travel Pack [or Solo® Pak or Refill Packet] Disposal: Put empty travel pack [or Solo® Pak or refill packet] in trash collection.

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

Optional Claims and Descriptors X" x Y" [wipes] % bigger [[quilted] wipes] [vs. X" x Y" wipes] # pre-saturated towelettes X" x Y" After use, just toss wipe(s) away Always ready to use An effective method to deodorize and disinfect against odor-causing organisms on hard nonporous surfaces listed on this label. An effective way to disinfect hard, non-porous environmental surfaces listed on this label. A non-woven disposable cloth for use in hospitals and other critical care areas where control of the hazards of cross contamination between treated surfaces is required. **Antibacterial Antimicrobial** A Sani-Surface® Brand Are pre-measured to have the recommended amount of germicidal solution, wipe after wipe. Assures proper dilution strength, product effectiveness and standardized technique. Bleach-free [formula] **Bonus** Can help reduce the risk of cross contamination on treated surfaces Cellulosic non-woven disposable cloth Contains [name of active ingredient], the [same] active ingredient used in [Brand-name] Contains [number] canisters [plus] [and] [number] refills Convenient Deodorize hard, non-porous surfaces [Use to] Deodorizes, and kills common household germs Diamond-embossed wipe is low-linting [for sensitive equipment surfaces] Disinfect and scrub clean Disinfect [and for touch-up clean] Disinfect external surfaces of ultrasound transducers Disinfect the precleaned surface Disinfects and deodorizes Disinfecting towelettes Disinfects grocery cart handles or shopping cart handles or grocery cart child seats or shopping cart child seats Disinfect[s] hard non-porous environmental surfaces listed on this label [Use to] Dispenses one wipe at a time Does not contain bleach Does not produce mist or overspray Double-sided scrubbing wipes Durable, low-lint wipe designed for sensitive equipment surfaces Easy Easy [and convenient] way to [touch-up] [bathroom] [office] everyday Easy drop-in refill[s] [Easy] pop-up-tub Easy start lid [package] Easy to use [easy to refill] [Economical] Refill[s] [one] [1] [two] [2] [three] [3] [four] [4] [various numbers] -pack [Economical] Refills [now] available **Economy** Effective against bathroom bacteria and viruses Effective against (the following micro-organisms on hard, non-porous surfaces) [list organisms] Eliminates odors Extra large disinfecting wipes Fast [Convenient] [Portable] way to disinfect hard non-porous surfaces For daily use Gets rid of [or] eliminates odors Helps prevent [bacterial] [viral] cross contamination [between] [hard non-porous] [surfaces] Includes count refill [pack] [contains] ___ wipes

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably

except for within the product primary brand name. F:shared\labels\pdi\\9480-6\2008\amend label VRE 022708.doc

February 27, 2008

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Just [or] simply wipe exterior toilet surface [or] bathroom germs away

Just [pull] wipe and toss

Kill germs and bacteria instead of germy paper towels, sponges and rags [Use this product to]

Kills germs and bacteria and viruses in the bathroom [or] on the exterior toilet surfaces

Kills household [or] exterior toilet surface [or] bathroom germs

Kills odor-causing germs

Leaves [bathroom] [office] disinfected [and smelling fresh]

Multi-pack

Multi-purpose disinfectant [Multi [-refill] pack]

New and improved [use this for 6 months after announced improvement]

New thicker wipe with diamond-embossed design

New larger, thicker wipe [with diamond-embossed design]

Next wipe pops up automatically [everytime] [!]

No canister needed

No measuring

No mixing

No sponges, no rags, no buckets, no mess

Non-woven disposable cloth

Now with [%] more towel [use this for 6 months after converting to larger towel]

Now with [#] more wipes [use this for 6 months after converting to a larger number of towels]

On-the-go disinfectant

Perfect for disinfecting exterior toilet surfaces -or- around the exterior toilet surface

Pop-up dispensing

Pop-up [top]

Portable

Premeasured

Premixed

Premixed, premeasured, premoistened

Premoistened

Pull n/ Go [pack]

Quick

Quick [and easy] [and convenient] way to disinfect

Quick and easy way to disinfect bathroom [or] exterior toilet surfaces

Quick and easy way to disinfect hard, nonporous surfaces

Ready to Use [on the following hard non porous surfaces]

[Refill] package contains [one] [1] [two] [2] [three] [3] [four] [4] [various numbers] [wet] [premoistened] [wipe] [refill[s]] [roll[s]]

Refill [size] [pack] [value pack]

Refillable [with ___# wipes] [dispenser] refill [pack] [for dispenser]

Requires no mixing or measuring and are ready-to-use

Resealable pouch [package] [container] inside

Reuse your [empty] canisters [again [and again] [!]

Sample

Scrubbing power of a sponge in a disinfecting wipe

Starts killing [bacteria] on contact

Strong, durable diamond-embossed textured wipe deodorizes

Strong, durable low-lint wipe [designed for sensitive equipment surfaces]

Tear at perforation

Textured diamond-embossed design deodorizes hard, non-porous surfaces

Textured diamond-embossed design

Thick, large wipe disinfects

Thick, textured wipe with diamond-embossed design

Time to reorder

Trial

Tub with pop-up action

Tub refill

Twin pack

Use to preclean or decontaminate critical or semi-critical medical devices prior to sterilization / high-level disinfection

The terms "wipe(s)", "towel(s)", "towelette(s)", and "cloth(s)" and the product name may be used interchangeably except for within the product primary brand name.

[Use to] refill[s] [count] [wipe] canisters or tubs

Value

Versatile

Virucide* including HIV-1, HBV and HCV applications and effective against Staphylococcus aureus Wet wipes

Where control of the hazards of cross contamination between treated surfaces is of prime importance [Wipes out] [Kills] [common] [household] [bacteria] [viruses*] [germs]

[Wipes out] [Kills] [the] flu virus, (Influenza A2/Hong Kong)

[Wipes out] [Kills] viruses* and bacteria [including the flu virus, (Influenza A2/Hong Kong)]

[Wiping] [soft] side for disinfecting

A bleach-free (formula) [a phenolic free (formula)]

© [insert year] [insert company name]

3 minute claims : [if TB and/or VRE is included on the label add footnote for TB and VRE as shown,

otherwise leave off footnote and mark]

Disinfects [in [just] three [3] minutes^]

Disinfects hard, non-porous surfaces [in 3 minutes^]

Disinfects and deodorizes [in 3 minutes^]

Kills bacteria in 3 minutes ^

Kills [list one or more organisms][in 3 minutes^]

The 3-minute^A germicidal wipe [disinfectant wipe]

Thick, heavy duty wipes are bactericidal and virucidal in 3 minutes^

[Wipes out] [Kills] [eliminates] [list organisms] in [just] [3 minutes ^]

^ 5 minutes for TB and VRE

5 minute TB claim:

Kills TB in 5 minutes

1 [A footnote can be used to list organisms shown on page 2. Bacteria and virus can be separated into footnotes 1 and 2 if desired.]

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CLEANING: [cleaning directions and claims have been grouped on this page (they were previously incorporated into other parts of the label)]

DIRECTIONS FOR USE:

CLEANING: Wipe surface with towelette until clean. Let air dry.

CLAIMS:

An effective method to clean against odor-causing organisms on hard non-porous surfaces listed on this label.

A One Step cleaner [and disinfectant] (except precleaning is required for heavy soil, blood and body fluids)

Cleans

Cleans and disinfects

Cleans, deodorizes, and kills common household germs

Cleans, disinfects and deodorizes

Cleans grocery carts and shopping carts

Diamond-embossed pattern [texture] provides effective cleaning

Easy One Step Cleaning [and disinfecting] (except precleaning is required for heavy soil, blood and body fluids)

Leaves [bathroom] [office] clean [and disinfected] [and smelling fresh]

Leaves bathroom fresh and clean in [just] minutes

Multi-purpose cleaner [Multi [-refill] pack]

New thicker and larger diamond-embossed wipe cleans more surface area [use this for 6 months after converting to larger towel]

Perfect for cleaning [and disinfecting] around the toilet

Premoistened [wet] household cleaning wipe

Premoistened with specially formulated cleaners to handle daily clean-ups without bottles, sponges or buckets [This product is]

Quick [and easy] [and convenient] way to clean [and disinfect]

Quick and easy way to clean [and disinfect] bathroom -or-exterior toilet surfaces

Quick and easy way to clean [and disinfect] hard, nonporous surfaces

[So] surfaces are more than [just] [clean] [they're] [disinfected]

[Soft] side for [cleaning] dirt away

Strong, durable diamond-embossed textured wipe cleans [and deodorizes]

Textured wipe for effective cleaning

Textured diamond-embossed design cleans hard, non-porous surfaces

Textured diamond-embossed design helps remove soil from surfaces

[Textured] [scrubby] [rough] side for [scrubbing] [cleaning] [removing] [wiping] [tough] [stains] [soils] [messes]

Thick, large wipe cleans

Wipe away odors

[Wipes out] [Kills] germs that cause odors

[Wipes out] [Kills] germs [while it cleans]

[Wiping] [soft] side for [wiping] dirt away [and disinfecting]

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









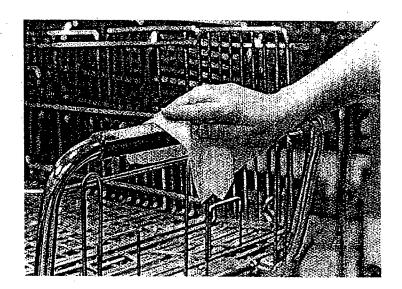
NOT A BABY WIPE

NOT FOR USE ON SKIN

This graphic shows use of the wipe dispenser.

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





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

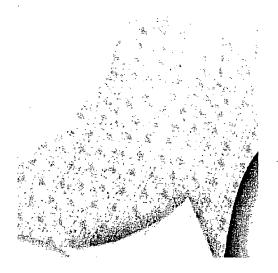


Not a Skin Wipe. For Use on Hard Surfaces Only.



Not a Skin Wipe. For Use on Hard Surfaces Only.

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



[One side scrubs] [One side wipes]