

9480-5

06/16/2004

1/14

JUN 16 2004

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

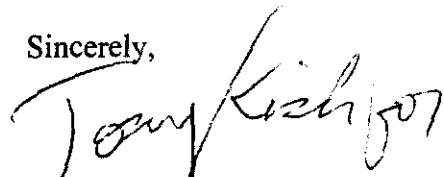
Subject: Sani-Cloth Germicidal Disposable Cloth
EPA File Symbol 9480-5
Your Notification Dated 6/15/04

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to provide a revised 13 page Master label (6/15/04 version) which adds pictures and graphics of certain listed uses, adds a lavender scent claim, revises the presentation and listing of virus claims, re-arranges the one-step claims to exclude HIV uses, adds certain use extensions such as grocery store carts, qualifies surfaces made of steel, Formica and glass as "...and other uses listed on this label consisting of stainless steel, Formica, and glass", and other minor changes, is acceptable.

This notification has been made a part of the official record for this product.

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

Sincerely,

A handwritten signature in black ink that reads "Tony Kish" followed by a stylized flourish.

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

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SANI-CLOTH
GERMICIDAL DISPOSABLE CLOTH

ACTIVE INGREDIENTS

n-Alkyl (68% C ₁₂ , 32% C ₁₄) dimethyl ethylbenzyl ammonium chlorides.....	0.14%
n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈) dimethyl benzyl ammonium chlorides	0.14%
Isopropyl Alcohol	8.00%
<u>OTHER INGREDIENTS</u>	91.72%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back [side] panel for additional precautionary statements

NET WT
[NET CONTENTS # OF CLOTHS SIZE]

[The following registration and establishment number information and registrant address information is mandatory, but may appear in any appropriate place on the label:]

EPA Reg. No.: 9480-5

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]

[Manufactured by:]
PDI, The Healthcare Division of Nice-Pak Products, Inc.
Two Nice-Pak Park
Orangeburg, NY 10962-1376
[For information call: *[phone number to be inserted]*] *[website address]*

THE INFORMATION IN THIS BOX IS NOT PART OF THE LABELING

Statements in brackets [] are optional or instructional. Italicized words in brackets are not included. Sequence 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.

PRECAUTIONARY STATEMENTS:

Hazards to humans and domestic animals.

CAUTION: Avoid contact with eyes.

FIRST AID

If in eye: 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.

[[All statements below within the brackets (this page and all of pages 3 and 4) are optional; choose from the following as appropriate; location is optional:]]

[Lemon Scent]

[Citrus Scent]

[Orange Scent]

[Floral Scent]

[Fresh Air Scent]

[Mint Scent]

[Lavender]

[Lavender Scent]

[Fresh Lavender Scent]

[Scent of Lavender]

[Sani-Cloth Germicidal Disposable Wipes [or this product] help[s] control common household germs on treated surfaces while keeping your office [or workplace or station or business] clean and dust-free]

[Sani-Cloth Germicidal Disposable Wipes [or this product] control[s] the spread of common household germs on ~~most~~ treated hard, non-porous surfaces [and has a clean, fresh scent]]

[For use in critical care areas [Where control of the hazards of cross contamination between treated surfaces is of prime importance]]

[Antibacterial]

[Aids in reducing [or in the reduction of] cross contamination between treated surfaces]]

[Bactericidal]

[Virucidal* [or] Kills viruses* * Influenza A2/Hong Kong (Hong Kong flu), Herpes Simplex Type 2]

[Kills virus* * Influenza A2/Hong Kong (Hong Kong flu)]

[Effective in 5 minutes against Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, and Klebsiella pneumoniae]

[Kills Staphylococcus aureus and Salmonella choleraesuis]

[Kills common household germs bacteria Staphylococcus aureus and Salmonella choleraesuis]

[Exhibits effective virucidal activity; kills Influenza A2/Hong Kong (representative of the common flu virus) and Herpes Simplex Type 2 (causative agent of genital herpes)]

[Kills Influenza A2/Hong Kong (Hong Kong flu) and Herpes Simplex Type 2]

[Also Effective against flu virus Influenza A2/Hong Kong (Hong Kong flu)]

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[Disinfects][+] *[the "+" next to disinfects leads to the following located on the same label panel:]*

[+Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, and Klebsiella pneumoniae]

[An effective way to disinfect hard, non-porous environmental surfaces]

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

[Cleans and disinfects]

[Cleans, deodorizes and disinfects]

[Cleans and disinfects common hard, non-porous surfaces]

[Effectively disinfects common hard, non-porous household surfaces]

[Use to clean, deodorize, and disinfect hard, non-porous surfaces in the nursery]

[Kills many common household bacteria and viruses*]

[Disinfects hard, non-porous environmental surfaces]

[Disinfects environmental surfaces]

[Nursery wipes]

[Household surface wipes]

[Telephone [cleaner [and]] disinfectant wipes]

[A disinfectant cloth for use on telephone surfaces and other telecommunications equipment surfaces]

[Cleans and disinfects [cell phone surfaces] [telephone surfaces,] [telephone equipment surfaces,] [dictating equipment surfaces,] [and other telecommunications equipment [surfaces] [devices]]]

[Disinfects headsets and telephones]

[Antibacterial Cell Phone wipe]

[Quick drying]

[Assures proper dilution strength for product effectiveness and standardized technique]

[Quaternary dispersal with no hazard of cross contamination]

[Non-woven disposable cloth]

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

[Convenient]

[Premeasured]

[Premoistened]

[Disposable]

[No mixing]

[Moist Wipes]

[Strong, Real Cloth Wipes]

[Pre-Moistened Towelettes]

[Multi-purpose cleaner]

[Multi-purpose cleaner and disinfectant]

[To Clean and Deodorize]

[Cleans effectively]

[Use on hard, non-porous surfaces only. [Test wipe on small inconspicuous area first.]]

[To Clean: Wipe surfaces and let air dry]

[For most hard, non-porous surfaces]

[Not recommended for natural marble, unpainted wood, brass, or colored grout]

[Bonus - [number to be inserted] [free] towels]

[number to be inserted] towels for the price of [price to be inserted]

[Now with [number to be inserted] extra towels]

[More towels]

[number to be inserted] towels free!]

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[Value Pack]
 [New, [number]% larger towels than before] [use this for 6 months after converting to larger towel]
 [Convenient, quick and easy cleaning all around your [home] [business] [office] [workplace]]
 [Each pre-moistened and disposable wipe cleans, deodorizes and kills common household germs all around your [home] [business] [office] [workplace]]
 [These wipes are a convenient and quick way to disinfect surfaces all around your [home] [business] [office] [workplace]]
 [The uniquely designed cap with recessed reservoir enables you to keep every wipe its freshest...even the leftovers from your last pull]
 [Effectively disinfects in the presence of organic soil (5% blood serum)]
 [Bath and Kitchen wipes]
 [Bath and Kitchen wipes for hard, non-porous surfaces]
 [Bath and Kitchen disinfectant wipes]
 [Use wipes to kill Influenza A2/Hong Kong on bath and kitchen hard, non-porous surfaces]
 [Use wipes to kill Salmonella, and Staphylococcus on bath and kitchen hard, non-porous surfaces]
 [Computers [and keyboards]]
 [Quick and Easy Cleaning Everywhere]
 [Disinfects common household kitchen and bathroom bacteria]
 [Kills Common [Kitchen] [Household] [Bathroom] Germs]
 [Use to disinfect shopping [or grocery] cart handles and shopping [or grocery] cart child seats]
 [Wipe down shopping [or grocery] cart handles and child seats]
 [Guaranteed quality every day]

[if one of the following one step cleaner claims is used:]

[A One Step** Cleaner/Disinfectant]

[An Effective One-Step** [Cleaner-] Disinfectant]

[Easy, One Step** Cleaning and Disinfecting]

and HIV-1 claims are included on the label, then the following also must be included on the label:]

***a pre-cleaning step is required for HIV-1*

[if ultrasound directions/claims are included on label then add: and ultrasound transducers [or probes]]

[if HIV is not listed on the label, any of the three one step cleaning/disinfecting claims may be used without the asterisks and phrase requiring pre-cleaning.]

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[choose from the following areas of use as appropriate; they may be listed in any order; at least one use site (including corresponding list of surfaces) must be used on the label; "Kitchen" areas of use must be included if "food contact surfaces" directions (see next page) are used.]

[AREAS OF USE

- [Kitchen** [Counter tops,] [exterior surfaces of [or outside of] appliances,] [sinks,] [faucets,] [table tops]] [exterior surfaces of [or outside of] refrigerators,] [exterior surfaces of [or outside of] stove]
- [Bathroom: [Toilet seats [and] [outside surfaces of toilets,] [bathroom fixtures,] [vanity tops,] [shower stalls,] [bathtubs,] [tiles,] [sinks]]
- [General use: [Doorknobs,] [laundry rooms,] [garbage cans,] [pet areas] [telephones,] [cell phones,] [telephone equipment surfaces,] [dictating equipment surfaces,] [and other telecommunications equipment [surfaces] [devices]] [headsets] [computers [and keyboards]] [car,] [desktop,] [office,]
- [Nursery: [Changing tables,] [cribs,] [diaper pails,] [trash cans,] [toys]
- [Grocery Stores, and/or [Shopping Centers, and/or [Delicatessens]: Disinfects [grocery cart handles,] [shopping cart handles,] [grocery cart child seats,] [shopping cart child seats] [and other hard non-porous surfaces] [Cleans [grocery carts] [shopping carts]

[The following is required if kitchen uses are included: [A thorough rinse with potable water is required for surfaces in direct contact with food.]**

[Optional: None, one, or both of the following paragraphs may be used as appropriate; paragraph # "B" may be used before "A" on the label if both are used]

[A]

[Hospital and Health Care Settings]

[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. Use on hard, non-porous surfaces and equipment including tables, carts, metal baskets, counters, cabinets, telephones [and other uses listed on this label consisting of stainless steel, Formica, and glass]. Some organisms are removed from the surface by thoroughly wiping the surface with the towel. Most remaining organisms are killed within five (5) minutes by exposure to the liquid in the towel.]

[B]

[B 1] **[Areas of Use:** Hard, non-porous surfaces in: [Surgery,] [Hospitals,] [Emergency Room,] [E.R.,] [Recovery Room,] [ICU,] [CCU,] [Anesthesia,] [Laboratory,] [Physical therapy,] [Respiratory therapy,] [Radiology,] [X-Ray,] [CAT Lab,] [New-born nursery,] [Pediatrics,] [Central Supply,] [Operating Room,] [Nursing homes,] [Home Health Care,] [Physician's offices,] [Dental offices,] [Ambulances,] [Clinics] [Hospices,] [Healthcare settings] [Doctor's offices]

[Section B 1 must be used if section B2 (below) is on the label]

[B 2] **[May be used on:** Hard, non-porous surfaces of: [Ultrasound [transducers or probes]], [Exam tables,] [Gurneys,] [IV poles,] [Bed railings,] [Outside surfaces of equipment,] [Toilet seats [and] [outside surfaces of toilets,] [Tables,] [Chairs,] [Stretchers].

[If paragraph A and/or paragraph B are used, then all of the following paragraph must be used on label.]

["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."]

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DIRECTIONS FOR USE

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

[Use one of the following as applicable to type of container.]

TOWELETTE [or WIPE] [or TOWEL] [or CLOTH]**[DISPENSER 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:

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

[PACKET:

Tear open packet. Unfold wipe.]

[Use one or more of the following as appropriate; they may be used in any order as long as the entire paragraph is used; food contact directions must be used if "kitchen" is one of the areas of use or listed in the claims section:]

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

TO DISINFECT:**[NON-FOOD CONTACT SURFACES**

Use a wipe to remove gross filth [or heavy soil]. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for a full five (5) minutes. Use additional wipe(s) if needed to assure continuous 5 minute wet contact time. Let air dry.]

[FOOD CONTACT SURFACES

Use a wipe to remove gross filth [or heavy soil]. Unfold a clean wipe and thoroughly wet surface. Treated surface must remain visibly wet for a full five (5) minutes. Use additional wipe(s) if needed to assure continuous 5 minute wet contact time. Let air dry followed by a thorough potable water rinse.]

[ULTRASOUND TRANSDUCERS

For use on external surfaces of 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. Treated surface must remain visibly wet for a full five (5) minutes. Use additional Use additional wipe(s) if needed to assure continuous 5 minute wet contact time. Let air dry.]

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[The following headings are optional; choose as appropriate:]

[Hospital Use] [Nursing Homes] [Doctor's Offices] [Hospices] [Healthcare Settings]

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[If directions for HIV are to be used, then use the following heading:]

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

[Use A,B,OR C:]

[A]

***KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/ OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in 30 seconds at room temperature (68° - 77°F or 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 1 (HIV-1) (associated with AIDS).

[B]

***KILLS HIV-1(AIDS VIRUS) ON THE PRE-CLEANED EXTERNAL SURFACES OF ULTRASOUND TRANSDUCERS [PROBES] PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in 30 seconds at room temperature (68°-77°F or 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 1(HIV-1) (associated with AIDS).

[C]

***KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED ENVIRONMENTAL SURFACES/ OBJECTS AND PRE-CLEANED EXTERNAL SURFACES OF ULTRASOUND TRANSDUCERS [PROBES] PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in 30 seconds at room temperature (68° - 77°F or 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 1 (HIV-1) (associated with AIDS).

[If paragraph A, B, or C are used, then all of the language below must be used on label:]

PERSONAL PROTECTION: When using this product, 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 surfaces and objects before disinfection by the germicidal cloth. Open and unfold first germicidal cloth to remove gross filth [heavy soil].

DISPOSAL OF INFECTIOUS 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 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 is not sufficient for the other non-HIV organisms listed on this label. Therefore a 5 minute wet contact time must be used for all listed non-HIV organisms.

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

[A]

STORAGE AND DISPOSAL

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

Dispenser: Do not reuse empty container. Wrap container and put in trash collection.

[B]

STORAGE AND DISPOSAL

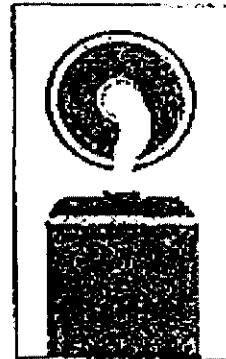
Towelette: Do not reuse towelette. Dispose of used towelette in trash. Do not flush in toilet.

Travel Pack [or Packet]: Put empty travel pack [or packet] in trash collection.

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*[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.]

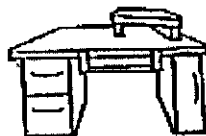
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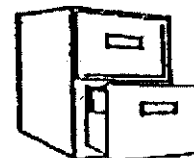
[The following graphics and statements are optional.]
They are used to show examples of places the product can be used]



CAR



DESKTOP



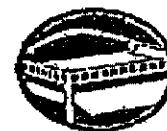
OFFICE



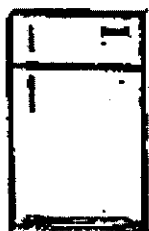
DOOR KNOB



FAUCET



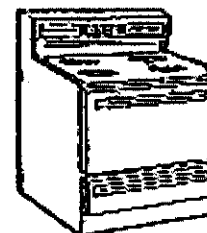
CHANGING TABLE



EXTERIOR OF
REFRIGERATOR



KITCHEN COUNTERS
AND SINKS



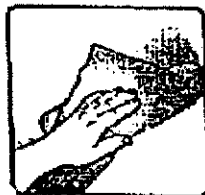
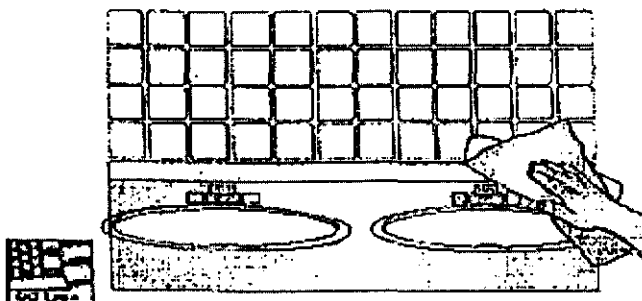
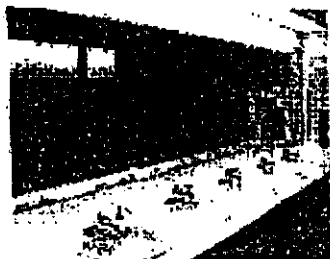
EXTERIOR OF
STOVE

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[The following graphics and statements are optional.]
They are used to show examples of places the product can be used]

12/14



TUB



SHOWER
STALLS



PHONES

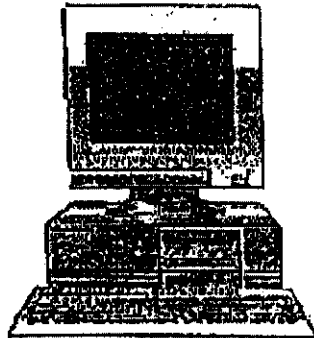
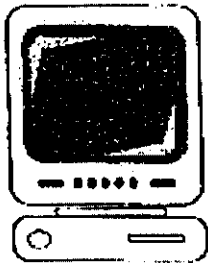


TOILET
SEATS

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Statements in brackets [] are optional or instructional. Italicized words in brackets are not included. Sequence 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.

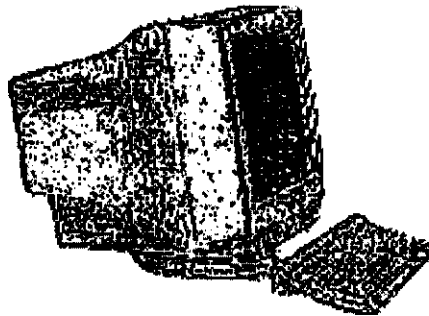
[The following graphics and statements are optional.]
They are used to show examples of places the product can be used]



COMPUTERS



COMPUTER KEYBOARDS

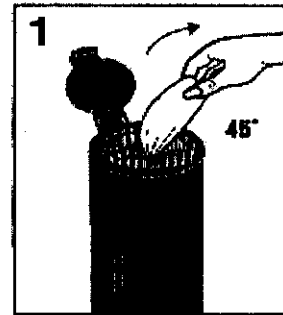


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[The following graphics and statements are optional.]
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14/14



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