

9402-9

06-01-2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN - 1 2004

Eliot Harrison
Agent for Kimberly Clark
Lewis and Harrison
122 C St., NW Suite 740
Washington, D.C. 20001

Subject: Kimberly-Clark KIMTECH Pre-Moistened Sanitizer Wipe
EPA Registration Number: 9402-9
Application Dated: April 14, 2004
Receipt Date: April 15, 2004

Dear Mr. Eliot Harrison:

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

- revise label language

Acceptable Data

The submitted efficacy MRIDs 458633-01 through -07 supports this registration. This data was performed using your product on rough plastic to simulate the use of this product on complex surfaces (i.e. textured undamaged plastic).

Conditions

1. Revise page 2 to be in agreement with the last stamped label of 4/8/03 as follows: "...Kills Staphylococcus aureus (Staph), & Escherichia coli (E. coli) & Listeria monocytogenes (Listeria) & Salmonella choleraesuis (Salmonella) & Shigella boydii (Shigella) & Klebsiella pneumoniae..." You may not use any abbreviations such as "staph" or "E. coli" unless they are immediately preceded by the complete name of the organism.

CONCURRENCES

SYMBOL	7510C							
SURNAME	S. Clark							
DATE	6/1/04							

2/11

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2. Delete the following surfaces from the "accessible food contact surfaces of" section on page 2 as these items have food contact surfaces which cannot be fully accessed with a wipe: slicers, choppers, beverage machines, soft serve ice cream machines, ice machines, meat grinders, griddles, steam tables, broilers, blenders, juicers, coffee machines, espresso machines, food mixers, backsplashes, and ovens.

3. Revise page 2 to specify the food contact portion of food and meat thermometers as follows: "...probe portion of food and meat thermometers..."

4. Since your product only includes directions for use of the wipe as a cleaner for non-food contact surfaces, revise page 3 by correcting statements 14, 18 and 19 as follows: "One step removal of tough grease and grime on non-food contact surfaces.", "[Great for][Effective for][Works for] sanitizing of food contact surfaces and food processing equipment." by deleting "quick cleaning and" and "[Great for][Effective for][Works for] quick sanitizing and touch ups on food contact surfaces and food processing equipment." by deleting "cleaning."

5. Revise page 4 by placing the following surfaces in the "and exteriors of" section as these items have food contact surfaces which cannot be fully accessed with a wipe: slicers, choppers, food mixers, backsplashes, and ovens.

65. As per the Agency letter of 9/16/03, revise page 4, 5th statement to read: "Kills 99.999% of bacteria in 60 seconds on smooth and textured surfaces."

7. Since your product only includes directions for use of the wipe as a cleaner for non-food contact surfaces, revise page 5 by correcting statements 9, 13, 14 and 16 as follows: "[Durable wipe for multi-surface cleaning and sanitizing of non-food contact surfaces.]", "[Wipes away grease and grime on non food contact surfaces.]", "[One large wipe for cleaning and extended use on non food contact surfaces.]" and "[Wipes away grease spatters on non food contact surfaces.]"

8. Revise page 6 by deleting the claim "Alcohol Free" as the absence of an ingredient is a misleading statement prohibited by 40 CFR 156.10 (a) (5) (I) and/or 40 CFR 156.10 (a) (5) (viii). It is an implied safety claim that there could be a safety issue associated with products containing alcohol.

9. Revise the 9th statement on page 6 to read as follows: "[Kills common household bacteria.]" A claim to clean bacteria is not accurate. Your product can clean a surface as well as kill bacteria by the sanitizing action of the active ingredients.

CONCURRENCES

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3/11

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10. Delete the section on page 7 beginning: "Do not use to sanitize utensils..." and ending "...thoroughly contacted by the wipe." and replace with the following which is the required text for food contact sanitizing wipe products. This statement has been developed in conjunction with the Food and Drug Administration:

"Do not use to sanitize glassware, cookware, eating utensils, and wood cutting board. Do not use to sanitize food preparation surfaces what 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."

11. Revise the directions "To Sanitize: For non-food contact surfaces and For food contact surfaces" by deleting the brackets [] as the statements "Do not reuse dried out wipes." are not optional.

12. On page 7, revise the "To Sanitize" instructions by correcting the product name to read: *Kimberly-Clark KIMTECH Pre-Moistened Sanitizer Wipe.*

General Comments

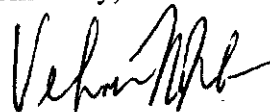
A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions or comments concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure: Stamped Label
7510C:T.Lantz:5/28/04:9402-9h

CONCURRENCES

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4/11

Note to reviewer: All text in brackets [...] is optional and may or may not be included on a final label. All text in braces {...} is administrative and will not appear on a final label. Portions or all of the label may be bilingual.

{FRONT PANEL}

• **KIMBERLY-CLARK KIMTECH® PRE-MOISTENED SANITIZER WIPE**

ACTIVE INGREDIENTS:

Octyl decyl dimethyl ammonium chloride	0.0120%
Dioctyl dimethyl ammonium chloride	0.0048%
Didecyl dimethyl ammonium chloride	0.0072%
Alkyl (C14, 50%; C12, 40%; C16, 10%) dimethyl benzyl ammonium chloride	0.0160%

INERT INGREDIENTS:.....99.9600%

TOTAL INGREDIENTS 100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

See back panel for additional precautionary statements

NET WT 30.53 oz. (865 grams) {Number may change prior to commercialization}
NET CONTENTS 30 {Number may change prior to commercialization} Pre-Moistened Wipes 12"
x 12" (30.48 x 30.48 cm)

E. P. A. Reg. No. 9402-9
E. P.A. Est. No. 009402-TX-001 {Number may change based on manufacturing location.}

**ACCEPTED
with COMMENTS
in EPA Letter Dated:**

JUN 1 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 9402-9

{¹ note to reviewer: all one-step claims will only be used in conjunction with non-food contact surfaces}
{² note to reviewer: these phrases will only be used in conjunction with the updated exclusion statement on the back panel under Directions for Use.}

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{FRONT OR BACK PANEL MARKETING CLAIMS}

[[Kills] [Effective against] 99.999% of Staphylococcus aureus [ATCC 6538], Escherichia coli [ATCC 11229], Escherichia coli O157:H7 [ATCC 43895], Listeria monocytogenes [ATCC 15313] [ATCC 19115], Salmonella choleraesuis [ATCC 10708], Shigella boydii [ATCC 9207], Klebsiella pneumoniae [ATCC 4352], in 60 seconds on hard non-porous food contact surfaces]
[Makes] [sanitizing] [quick and easy.]
[[Kills] [bacteria], [For use] on hard non porous food and non-food contact surfaces.]
[Use areas] [Sanitizes hard, non-porous food contact surfaces at the following locations] [Kills [Staph] [Staphylococcus aureus], & [E. coli] [Escherichia coli], & [Listeria monocytogenes] [Listeria], & [Salmonella choleraesuis] [Salmonella], & [Shigella boydii] [Shigella], & [Klebsiella pneumoniae] at the following locations] {note to reviewer: at least one of these options must be included}
<ul style="list-style-type: none"> [restaurants], [delis], [cafeterias], [hotels], [food processing establishments], [day care settings], [institutional, hospital, and school [kitchens]], [bars], [grocery stores], [supermarkets], [fast-food chains], [produce areas], [checkout lanes], [food processing plants], [airplanes], [poultry/meat packing facilities], [and other food service establishments or establishments with food preparation areas].
[Kills bacteria on];
- [hard non-porous food contact surfaces such as...]
<ul style="list-style-type: none"> [[tables], [chairs], [grocery store carts], [food trays], [microwaves], [stove tops], [appliances], [high chairs], [kitchen] [counters], [drain boards], [cabinets], [hoods], [food cases], [non-porous shelves], [refrigerators], [freezers], [food preparation tables], [scales], [non-wood cutting boards], [self service condiment areas], [self service serviceware areas], [and similar hard non-porous food contact surfaces except for those excluded by the label].
- [[and] accessible [food contact] surfaces of...]
<ul style="list-style-type: none"> [slicers], [choppers], [beverage machines], [soft serve ice cream machines], [ice machines], [meat grinders], [fryers], [grills], [condiment organizers], [salad bars], [griddles], [vending machines], [coffee machines], [espresso machines], [steamers], [steam tables], [warmers], [broilers], [hot plates], [blenders], [juicers], [food and meat thermometers], [food mixers], [backsplashes], [ovens], [and similar hard non-porous food contact equipment surfaces except for those that should be sanitized in a warewashing machine or sink].
[Kills bacteria on];
[[Cleans and Sanitizes] in one step]; ⁽¹⁾
- [hard non-porous non-food contact surfaces such as...]
<ul style="list-style-type: none"> [[bathroom] [sinks], [faucets], [toilet seats and rims], [towel dispensers], [hand railings], [infant changing tables], [stall doors], [bath tubs], [showers], [hampers], [tiled walls], [telephones], [diaper pails], [door knobs], [playpens], [cribs], [vanities], [cash registers], [dining] [tables] [chairs], [grocery store carts], [floors], [booster chairs], [kitchen] [counters],

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10/11

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[hoods], [non-porous shelves], [garbage cans], [high chairs], [display cases], [and other hard non-porous non-food contact surfaces at work and home.]
- [[and] exteriors of...]
<ul style="list-style-type: none"> • [beverage machines], [appliances], [soft serve ice cream machines], [ice machines], [meat grinders], [fryers], [grills], [condiment organizers], [salad bars], [griddles], [vending machines], [coffee machines], [espresso machines], [steamers], [steam tables], [warmers], [broilers], [vents], [freezers], [blenders], [juicers], [food cases], [and similar hard non-porous non-food contact equipment surfaces at work and home.]
[Assists] [Aids] [in your attempt to develop best practices in sanitization.]
[No rinsing is required.]
[Stops] [Eliminates] [Reduce][Halts][Aids in the reduction of] [bacterial transfer between dirty rags and surfaces.]
[Reduces][Aids in the reduction of] [cross contamination][of treated surfaces].
[[Especially] [designed] [formulated] for use on hard non-porous food contact surfaces where controlling cross contamination is critical.]
[[Especially] [designed] [formulated] for use on hard, non-porous, food contact and food preparation surfaces where the control of cross contamination is of prime importance.]
[Effective [even] on moderately soiled surfaces.]
[Effective in the presence of 5% [serum.] [soil.]]
[Effective in moderate soil.]
[One step removal of tough grease, grime]
[For use on Food Contact Surfaces & Non-food Contact Surfaces.]
[Kills Staphylococcus aureus, Escherichia coli, Escherichia coli O157:H7, Listeria monocytogenes, Salmonella choleraesuis, Shigella boydii, Klebsiella pneumoniae in 60 seconds.]
[[Great for use] [Effective] [Works] on food contact surfaces [and food processing equipment.]] ⁽²⁾
[[Great for] [Effective for] [Works for] quick cleaning and sanitizing of food contact surfaces and food processing equipment.] ⁽²⁾
[[Great for] [Effective for] [Works for] quick sanitizing [and cleaning] touch ups on food contact surfaces and food processing equipment.] ⁽²⁾
[[Works on] [Effective on] [Kills bacteria on] countertops]], [plastic table tops] [and] [food refrigeration equipment.]]
[Powerful enough to kill bacteria.]

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7/11

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[For all plastic and other surfaces.]
[For use on smooth or textured surfaces!]
[Multi-purpose, Multi-surface]
[Durable wipe!]
[[Kills more than 99.999% foodborne bacteria in 60 seconds] on smooth and textured surfaces.]
[[KIMTECH® Prep Surface Sanitizer Wipe-] An innovation in sanitation]
[[KIMTECH® Prep Surface Sanitizer Wipe-] ...taking the tech out of the task!]
[Ready to use]
[Non-corrosive]
[Assures the right product and dilution [for surface sanitation] every time.]
[The simple [answer] [solution] to complex surface sanitizing needs.]
[Surface Sanitation [done] the easy way.]
[The [fast], [easy], [effective], and [convenient] way to sanitize surfaces.]
[No [mixing], [measuring] or [rinsing] required]
[No more test strips]
[Simple and easy to use]
[[No mess], [No dilution], [No rinse], [No dirty rags]]
[Kills bacteria in the wipe and on the surface.]
[[Formulated] [Designed] to have the necessary active concentration for food contact surface sanitizers.]
[Sanitation made easy.]
[Provides quick and easy protection against bacteria for both customers and employees on treated surfaces.]
[[Easy to use.] [Just wipe and let air dry to sanitize surfaces].]

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8/11

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[No need to store or handle large bulky buckets.]
[Eliminates hard water issues].
[No-Rinse, [food contact], hard surface sanitizing wipe.]
[Advanced wiper technology –[kills] [removes] dirt & bacteria]
[Advanced towel technology from the [Towel Company][first name in towels and tissues.]]
[One large wipe [for extended cleaning and sanitizing] [with lots of sanitizing power]]
[Industrial Size, Industrial Sanitizer]
[There’s plenty of sanitizer for those tough kitchen jobs!]
[Durable wipe for multi-surface cleaning and sanitizing.]
[That’s one tough towel!]
[NO ripping, tearing, or shredding!]
[Stays together, Won’t shred!]
[Wipes away grease and grime]
[One large wipe for easier cleaning and extended use]
[Be wise, sanitize]
[Wipes away grease splatters]
[Food Service Sanitizing Wipes]
[Big Sheet Size 12” x 12”]
[One-step cleaner-sanitizer for non-food contact surfaces.]
[No pre-cleaning required for non-food contact surfaces.]
[Get a fresh, clean [KIMTECH®] wipe every time.]
[One Wet Wipe!]

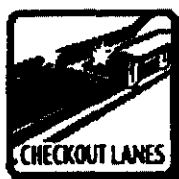
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9/11

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[Alcohol free.]
[Designed to be extra wet so users can sanitize longer.]
[Pre-moistened wipe engineered to stay wet longer for extended sanitizing.]
[Anti-bacterial]
[Anti-microbial]
[[Bathroom] [Kitchen] surface wipes.]
[Recommended for use on hard, non-porous, non-food contact surfaces as a one step sanitizer.]
[One-step no rinse sanitizer for hard, non-porous non-food contact surfaces.]
[Cleans and kills common household bacteria.]
[All applicable health inspection agency code requirements must be followed for cleaning, rinsing, and sanitizing.]



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10/11

{BACK PANEL}

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

Do not use to sanitize utensils, glassware, cookware, wood cutting boards, or other food contact equipment which could be cleaned or sanitized in a warewashing machine or sink. Do not use to sanitize other food contact surfaces which cannot be thoroughly contacted by the wipe.

TO SANITIZE:

For non-food contact surfaces: Use Kimberly-Clark KIMTECH® Pre-Moistened Sanitizer Wipe to clean and sanitize. Wipe enough for treated area to remain visibly wet for a minimum of 60 seconds. Let air dry. No rinsing required. [Do not reuse dried out wipes.]

For food contact surfaces: Cleaning and Sanitizing Procedure: Thoroughly clean all food contact surfaces using suitable detergents, brushes, sponges and other necessary equipment. Then rinse with potable water and sanitize with Kimberly-Clark KIMTECH® Pre-Moistened Sanitizer Wipe. To sanitize, wipe enough for treated area to remain visibly wet for a minimum of 60 seconds. Let air dry. Do not rinse. [Do not reuse dried out wipes.]

{**Note to Reviewer: Appropriate dispensing directions will be chosen to suit dispenser type.**}

DISPENSING DIRECTIONS

{for canister}: Remove lid by unscrewing from canister. Locate the first wipe in the center of the roll. [Pull first wipe up.] [Pull first wipe up about 6 inches.] [Pull first wipe up about 12 inches.] Thread first wipe through the opening in the center of lid (dispensing port). Screw lid back onto canister. Dispense by pulling wipe through the dispensing port [at an angle]. Dispenses one at a time. Remaining wipes feed automatically ready for next use. Close top when finished [to prevent moisture loss].

{for rigid top flexible flat pack/or rigid top tub}: Open top. Remove needed wipes. Close top when finished [to prevent moisture loss].

{for peel-back flexible flat pack}: Carefully pull back seal. Remove needed wipes. Reseal when finished [to prevent moisture loss].

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. Do not use for cleaning 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 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.

[Hot Line Number

You may also contact 1-800-XXX-XXXX for emergency medical treatment information]

14/11

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STORAGE AND DISPOSAL: Wipe: Do not reuse wipe. Dispose of used wipe in trash. **DO NOT FLUSH.** Dispenser: Store in original container in areas inaccessible to children. Do not reuse empty container. Discard in trash. Do not store near heat or open flame.

Manufactured [by] [for] Kimberly-Clark [Corporation] [Global Sales], [1400 Holcomb Bridge Rd.,] Roswell GA 30076

For more information call 1-800-472-6881

[ 1-800-472-6881]

[ kcpprofessional.com]

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