

9402-9

4/8/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 8 2003

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
Your Amendments Dated: December 30, 2002 and March 11, 2003
EPA Received Date: January 9 and March 12, 2003

Dear Mr Harrison,

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

- revise label language

Conditions

The Agency accepted graphics for this label on 11/15/02 via a notification. If your graphics defer from those which were reviewed by the Agency on 11/15/02 you must resubmit a label to the Agency for review.

Revise the label as follows:

1. Make the following revisions to page two:

A. Revise the fourth statement to read: "...[Kills *Staphylococcus aureus* (staph) and *Escherichia coli* (e. coli) at the following locations]..." You may not use any abbreviations such as "staph" or "e. coli" unless they are immediately preceded by the complete name of the organism.

B. Regarding the fifth statement: at least one site must be listed on any final printed label.

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SURNAME	J. Clark						
DATE	4/8/03						

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C. Regarding the eighth statement: at least one surface must be listed on any final printed label. Make the following additional modifications to this statement:

1. Delete the surface "non-wood cutting boards". The Agency feels that a towelette will not apply sufficient product to adequately sanitize the entire surface including all cracks, crevices, nicks and other imperfections due to the use of sharp objects against the surface on any type of cutting board, no matter what the surface composition.

2. Identify that this product is for "spot cleaning of floors".

3. Change the location of the brackets such that all the following text beginning with "and other similar..." is not optional: "...[non-porous shelves], [refrigerators] and similar hard non-porous food contact surfaces except for those excluded by the label."

D. Delete the sixteenth statement "[Handles [surface sanitization] [[the critical task[s]] in one easy step!]" It is unclear what is meant by "critical task."

E. Delete the eighteenth and nineteenth statements: "[Eliminates [chemical] confusion, mixing, and measuring all in one easy step!]" and "[Eliminates [chemical, mixing, and measuring] confusion all in one easy step!]" Both of these claims imply that this product is safer than other products on the market and thus are false and misleading.

2. Make the following revisions to page three:

A. Delete the fourth statement: "[One step cleaner sanitizer]". This product is a one step cleaner and sanitizer only on moderately soiled surfaces. This statement implies that the product is always a one step cleaner and sanitizer.

B. Revise the fifth statement to read: "[Sanitizes and cleans *moderately soiled surfaces* in one easy step]"

C. Delete the tenth statement: "[Single-step [cleaning and] sanitizing]" for the same reason identified in 2. A. above.

D. Delete the thirteenth statement: "[Food Service Swipes]". The term "swipe" does not adequately describe how to use this product; it implies that the user does not need to thoroughly wipe the surface.

E. Delete all of the following phrases in the fourteenth statement: "[One Swipe Sanitizer], [Swipe and Swish], [One Wipe, One Swipe], [Swipe away bacteria], [Swipe away worries],[Be wise, swipe and sanitize]." These phrases do not adequately describe how to use this product; they imply that the user does not need to thoroughly wipe the surface.

F. Delete the fifteenth statement: "[One Wipe, One Swipe-Bye, Bye Bacteria]"

G. Revise the seventeenth statement to begin as follows: "[[Effective one-step sanitizer for use] on Food]" as per the reasoning identified in item 2.A. above.

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3. Make the following revisions to page four:

A. Revise the "To Sanitize" directions by rearranging this section to begin exactly as follows:

"If surface is heavily soiled, use first Kimberly-Clark Kim Tech Pre-Moistened Sanitizer Wipe to pre-clean and remove heavy soil. After pre-cleaning, use second wipe to sanitize as directed below. Use one wipe to clean and sanitize lightly to moderately soiled surfaces. Treated surfaces must remain wet..." include the remainder of this section and end with the statement: "Do not reuse dried out wipes."

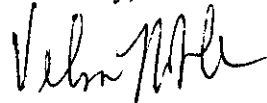
B. Delete the graphic "NSF registered, Category Code: 02, NSF Registration No 128441" in the bottom right corner of this page. The OPP Labeling Committee has discussed this logo. We find that we currently need more information and will continue to meet on this issue before a decision can be reached.

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.

Should you have any questions 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:4/4/03:9402-9e

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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)

EPA Reg. No. 9402-9
EPA Est. No. 009402-TX-001

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

APR 08 2003

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

9402-9

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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 & e-coli 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], [other food service establishments or establishments with food preparation areas].
[Kills bacteria on];
<p style="text-align: right;">APR 08 2003 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the pesticide, registered under EPA Reg. No. 9402-9</p>
<p>- hard non-porous food contact surfaces such as...</p> <ul style="list-style-type: none"> [[tables/chairs], [grocery store carts], [food trays], [stove tops], [appliances], [high chairs], [booster chairs], [dining room] [tables/chairs], [kitchen] [counters] [drain boards], [cabinets], [hoods], [food cases], [floors], [non-porous shelves], [refrigerators], and similar hard non-porous food contact surfaces except for those excluded by the label.]
- [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], other hard non-porous non-food contact 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 surfaces where controlling cross contamination is of prime importance.]
[[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.]
[[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.]
[[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.]

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[Effective [even] on moderately soiled surfaces.]	
[Effective in the presence of 5% serum.]	
[Effective in moderate soil.]	
[REDACTED]	
[Sanitizes and cleans in one easy step.]	
[No pre-clean [pre-cleaning] required on lightly or moderately soiled surfaces.]	
[One step to simple sanitation.]	
[No Pre-clean...No Problem]	ACCEPTED with COMMENTS in EPA Letter Dated:
[A single step solution to surface sanitation.]	APR 08 2013
[REDACTED]	Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.
[One Step, One Wipe]	9402-9
[One step removal of tough grease, grime and bacteria]	
[REDACTED]	
[REDACTED]	
[REDACTED]	
[From dirty to clean in 60 seconds.]	
[[Effective one-step sanitizing cleaner 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 on food-contact surfaces.]	
[[Great for use] [Effective] [Works] on food contact surfaces.]	
[[Great for] [Effective for] [Works for] quick cleaning and sanitizing of food contact surfaces.]	
[[Great for] [Effective for] [Works for] quick sanitizing [and cleaning] touch ups on food contact surfaces]	

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{BACK PANEL}

ACCEPTED
with COMMENTS
in EPA Letter Dated:

APR 08 2003

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

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide,

Do not use to sanitize eating utensils, glassware, cookware and food-processing equipment.

9402-9

{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].

TO SANITIZE: Use Kimberly-Clark KimTech® Pre-Moistened Sanitizer Wipe to clean and sanitize lightly to moderately soiled surfaces. Treated surfaces must remain wet for 60 seconds to achieve sanitization. Let air dry. Do not rinse. Discard wipe when wipe no longer wets the surface or becomes dry. Do not reuse dried out wipes. If surface is heavily soiled, use first wipe to pre-clean and remove heavy soil. After pre-cleaning, use second wipe to sanitize as directed above.

PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS AND DOMESTIC ANIMALS. Do not use for cleaning or sanitizing human skin.

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]

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]

[kcprofessional.com]

