

9402-9

12/17/2008

1/10

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 17 2008

Ms. Christina Swick
Agent for Kimberly-Clark Global Sales, Inc.
Lewis and Harrison
122 C Street, N.W., Suite 740
Washington, D.C. 20001

Subject: Kimberly-Clark KIMTECH Pre-Moistened Sanitizer Wipe
EPA Registration No.: 9402-9
Amendment Date: September 17, 2008
EPA Receipt Date: September 18, 2008

Dear Ms. Swick,

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

Conditions

Revise your label as follows:

1. Revise the first bullet on page two which begins: "[restaurants], [delis]..." to end with the following statement: "{note to reviewer: at least one of these options must be included}"
2. Revise the second bullet on page two which begins: "[tables], [chairs]..." to end with the following statement: "{note to reviewer: at least one of these options must be included}"
3. The statement on page three: "For all plastic and other surfaces" is too broad. Revise to read exactly as follows: "For all plastic and other surfaces listed on this label."
4. As previously requested, since your product only includes directions for use of the wipe as a cleaner for non-food contact surfaces, revise page five, thirteenth statement to read: "[One large wipe for easier cleaning and extended use on non food contact surfaces.]"
5. Correct the error on page six, seventh statement to read: "[Kills common household bacteria.]"
6. Your combined non-food contact and food contact "To Sanitize" directions are not acceptable and are not in agreement with DIS/TSS-17. Delete the entire section beginning: "To Sanitize..." and ending: "dried out wipes."

CONCURRENCES

SYMBOL	7510P							
SURNAME	S. Jantz							
DATE	12/16/08							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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Revise by adding the following as per the last stamped label and to bring these directions into agreement with DIS/TSS-17:

“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.]

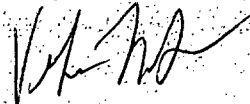
For food contact surfaces: Cleaning and Sanitizing Procedure: Remove gross food particles and soil by a preflush, or prescrape and when necessary, pre-soak using brushes, sponges and other necessary equipment. Then thoroughly wash with suitable detergent and rinse with potable water prior to application of sanitizer. To sanitize, wipe with Kimberly-Clark KIMTECH Pre-Moistened Sanitizer Wipe. 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.]”

General Comments

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

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 concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



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

Enclosure: Stamped Label
7510P:T.Lantz:12/15/08:9402-9j

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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.

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{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:
DEC 17 2008**

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}

<p>[[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]</p>
<p>[Makes] [sanitizing] [quick and easy.]</p>
<p>[[Kills] [bacteria], [For use] on hard non porous food and non-food contact surfaces.]</p>
<p>[Use areas] [Sanitizes hard, non-porous food contact surfaces at the following locations] [Kills [Staphylococcus aureus (Staph)], & [Escherichia coli (E. 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}</p>
<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].
<p>[Kills bacteria on];</p>
<p>- [hard non-porous food contact surfaces such as...]</p>
<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].
<p>- [[and] accessible [food contact] surfaces of...]</p>
<ul style="list-style-type: none"> • [fryers], [grills], [condiment organizers], [salad bars], [vending machines], [steamers], [warmers], [hot plates], [probe portion of food and meat thermometers], [and similar hard non-porous food contact equipment surfaces except for those that should be sanitized in a warewashing machine or sink].
<p>[Kills bacteria on];</p>
<p>[[Cleans and Sanitizes] in one step]; ^{1}</p>
<p>- [hard non-porous non-food contact surfaces such as...]</p>
<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], [hoods], [non-porous shelves], [garbage cans], [high chairs], [display cases], [and other hard non-porous non-food contact surfaces at work and home.]

^{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.

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.

- [[and] exteriors of...]
<ul style="list-style-type: none"> • [slicers], [choppers], [food mixers], [backsplashes], [ovens], [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 on non-food contact surfaces.]
[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] sanitizing of food contact surfaces and food processing equipment.] ⁽²⁾
[[Great for] [Effective for] [Works for] quick sanitizing and 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.]
[For all plastic and other surfaces.]

{¹ note to reviewer: all one-step claims will only be used in conjunction with non-food contact surfaces}

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[For use on smooth or textured surfaces!]
[Multi-purpose, Multi-surface]
[Durable wipe!]
[[Kills 99.999% of bacteria in 60 seconds] on smooth and textured surfaces.]
[[Kimberly-Clark KIMTECH Pre-Moistened 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].]
[No need to store or handle large bulky buckets.]

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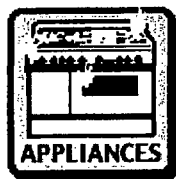
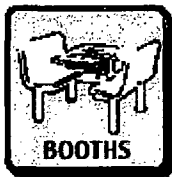
[Eliminates hard water issues].
[No-Rinse, [food contact], hard surface sanitizing wipe.]
[Advanced wiper technology –[kills] [removes] dirt & bacteria]
[Advanced towel technology from the[Towel Company]][first name in towels and tissues.]]
[One large wipe [for extended cleaning and sanitizing] [with 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 of non-food contact surfaces.]
[That’s one tough towel!]
[NO ripping, tearing, or shredding!]
[Stays together, Won’t shred!]
[Wipes away grease and grime on non-food contact surfaces.]
[One large wipe for easier cleaning and extended use]
[Be wise, sanitize]
[Wipes away grease splatters on non-food contact surfaces.]
[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!]
[Designed to be extra wet so users can sanitize longer.]

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[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.]
[Kills common household bacteria.]
[All applicable health inspection agency code requirements must be followed for cleaning, rinsing, and sanitizing.]



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

~~**TO SANITIZE:** For non-food contact surfaces, use Kimberly-Clark KIMTECH Pre-Moistened Sanitizer Wipe to clean and sanitize. For food contact surfaces, pre-clean to remove soil. Use Kimberly-Clark KIMTECH Pre-Moistened Sanitizer Wipe to sanitize. Treated surfaces must remain wet for 60 seconds to achieve sanitization. Let air dry. No rinsing required. 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].

{for Snap Top Canisters}: Flip open the dispensing flap with one hand, squeeze the body of the canister with the other and pull up firmly on the lid to remove entire cap from canister. Locate the wipe at the center of the roll, twist to a point, and thread through the small opening in the lid. Replace lid and pull wipe at a 45 degree angle; the next sheet pops up automatically. Always snap lid securely shut between uses 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.]


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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]

[ kcprofessional.com]

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