

9402-9

8-7-2002

1/7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobial Division (7510C)
1200 Pennsylvania Avenue N.W.
Washington, D.C. 20460

EPA Reg. Number:

9402-9

Date of Issuance:

AUG - 7 2002

NOTICE OF PESTICIDE:

- Registration
- Re-registration

(under FIFRA, as amended)

Term of Issuance:

This Notice of Registration expires on 8/7/03.

Name of Pesticide Product:

**Kimberly-Clark KIMTECH
Pre-Moistened
Sanitizer Wipe**

Name and Address of Registrant (include ZIP Code):

Kimberly-Clark Corporation
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that:

1. You submit and/or cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Add the phrase "EPA Reg. No. 9402-9."

Signature of Approving Official:

Velma Noble *Velma Noble*
Acting Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Date:

AUG - 7 2002

CONCURRENCES

SYMBOL	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS	DATE	INITIALS
7510C	8/2/02	J. Jack						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

2/7

page 2
EPA Reg. No. 9402-9

2. Efficacy data using a rough plastic surface (i.e. plastic cutting board) must be submitted by 2/7/03. This data must be generated using the protocol titled: "Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes." Refer to section 5.2.

3. The submitted data in item #2 above must be found to be acceptable in order for EPA to change the "Terms of Issuance" of this registration. If any of the submitted data are not found to be acceptable, this registration will automatically expire on 8/7/2003.

4. Make the following changes to the label and submit one copy of final printed label.

A. Revise the first statement on page 2 to read exactly as follows: "[Kill] [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."

B. Revise the third statement on page 2 to read exactly as follows: "[Kills] [bacteria], [For use] on pre-cleaned, hard non porous food and non-food contact surfaces and equipment."

C. Revise the seventh statement on page 2 to read exactly as follows: "hard non-porous food contact surfaces such as..."

D. Revise the eighth section on page 2 to read exactly as follows: "[tables/chairs], [grocery store carts], [food trays], [non-wood cutting boards], [microwaves], [stove tops], [appliances], [high chairs], [booster chairs], [dining room] [tables/chairs], [kitchen] [counters] and similar hard non-porous food contact surfaces except for those excluded by the label."

Your proposed language does not adequately convey to the user the surfaces of food processing equipment which could not be adequately sanitized with this product, and thus must be deleted. In addition, the protocol for "Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes" is not intended to "...address products for use on utensils, glasses, food containers, dishes, and food processing equipment."

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

page 3
EPA Reg. No. 9402-9

E. Revise the ninth statement on page 2 to read exactly as follows: "hard non-porous non-food contact surfaces such as..."

F. Revise the tenth statement on page 2 to read exactly as follows: "...[door knobs], other hard non-porous non-food contact surfaces at work and home."

G. Revise the twelfth statement on page 2 to read exactly as follows: "No rinsing is required." as comparative claims are not acceptable for pesticidal products.

H. Delete the thirteen statement on page 2: "[Less] [Fewer] [Eliminates] [mistakes in use.]"

I. Revise the sixteenth statement on page 2 to read exactly as follows: " [Especially] [designed] [formulated] for use on hard non-porous food contact surface where controlling cross contamination is critical."

J. Revise the second statement on page 3 to read as follows: "Do not use to sanitize eating utensils, glassware, cookware, and food processing equipment." by deleting the term "submersible."

K. Revise the directions "To Sanitize" by adding the following text: "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."

L. Revise the "First Aid" section by deleting the duplicate statement this section: "Have product container or label with you when calling a poison control center or doctor or going for treatment." This statement must only appear once in this section.

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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

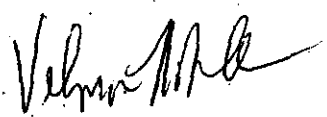
4/7

page 4
EPA Reg. No. 9402-9

A stamped copy of the label is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

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

Sincerely,



Velma Noble
Product Manager 31
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Enclosures: Stamped Label
Non-Residual Sanitization of Hard Inanimate Food
Contact Surfaces Using Pre-Saturated Towelettes

CONCURRENCES							
SYMBOL	7510C:T.Lantz:8/27/02:9402-9						
SURNAME							
DATE							

5/7

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-XXX {Registration number will appear on printed label}
E. P.A. Est. No. XXXXX {EPA Establishment number will appear on printed label}

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

AUG 07 2002
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

9402-9

6/7

ote 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 OR BACK PANEL MARKETING CLAIMS}

[Kill] [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] [pre-cleaned, hard non porous] [food and non-food contact surfaces and equipment.]
[Use areas] [Sanitizes hard, non-porous food contact surfaces at the following locations]
<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], [other food service establishments or establishments with food preparation areas].
[Kills bacteria on];
- [hard non-porous food contact surface, such as...]
<ul style="list-style-type: none"> [non-submersible] [dishes/choppers], [cutting boards], [tables/chairs], [grocery store carts], [food trays], [non-wood cutting boards], [microwaves], [stove tops], [appliances], [high chairs], [booster chairs], [dining room] [tables/chairs], [kitchen] [counters], [hard non-porous] [surfaces] [at work and home].
- [hard non-porous] [non-food contact] [surface, 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], [other] [hard non-porous] [non-food contact] [surfaces at work and home].
[Assists] [Aids] [in your attempt to develop best practices in sanitization.]
[Hard non-porous] [non-food contact] [surface, such as...] [no rinsing is required.]
[Less] [Fewer] [Eliminates] [mistakes in use.]
[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.]

ACCEPTED with COMMENTS in EPA Letter Dated:

AUG 07 2002

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

7/7

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.

{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 eating utensils, glassware, cookware, and ~~other~~ food processing equipment.

{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: Pre-clean by removing visible soil. Use KimTech® Pre-Moistened Santizer Wipe to sanitize. 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.

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 Kimberly-Clark Corporation, [1400 Holcomb Bridge Rd.,] Roswell GA 30076

For more information call 1-800-472-6881

[1-800-472-6881

[kcprofessional.com]

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 07 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as

Page 3 of 3 7/23/02 amended, for the pesticide,
Supersedes all labels dated prior to 7/23/02.

9402-9