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WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

August 9, 2002

MEMORANDUM:

Subject: Efficacy Review for EPA Reg. Nos.: 9402-O, "KIMTECH® PRE-MOISTENED SANITIZER WIPE"
DP Barcodes: D284446
Case No.: 071463

From: Emily Mitchell, M.S., Team Leader Emily Mitchell 8/12/02
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Formulation From Label:

Active Ingredient(s)	% by wt.
Octyl decyl dimethyl ammonium chloride	0.0120%
Dioctyl dimethyl ammonium chloride	0.0048%
Didecyl dimethyl ammonium chloride	0.0072%
n-Alkyl (50% C_{14}, 10% C_{16}, 40% C_{12}) dimethyl benzyl ammonium chlorides	0.0160%
Inert Ingredients(s)	99.9600%
	100.0000%

I BACKGROUND

The product 009402-O, KIMTECH Pre-Moistened Sanitizer Wipe, is being reviewed as a new end-use sanitizer for use on hard, non-porous food-contact and food contact surfaces. All studies were conducted at Hill Top Research, Inc. at Main and Mill Streets in Miamiville, Ohio 45147.

This data package contained one study (MRID Nos. 457089-1), Statement of No Data Confidentiality Claim, a copy of EPA Form 8570-35 (Data Matrix), and the proposed label.

Note: According to information in the data package, the applicant met with EPA Antimicrobial Division staff, on May 30, 2001. The efficacy studies conducted in support of this product registration and included in this data package are based on EPA comments received at this May meeting, EPA's letter dated June 21, 2002, and EPA's draft guidance entitled "Non-Residual Sanitization of Hard Inanimate Food-Contact Surfaces Using Pre-Saturated Towelettes" (April 12, 2001).

II USE DIRECTIONS

The product is designed to be used as a sanitizing wipe on hard non-porous surfaces for use on both food-contact and non-food contact surfaces in restaurants; bars; institutional, hospital and school kitchens; delis; food processing establishments; groceries; and other food service establishments, including homes.

This product is in ready-to-use form. The proposed label directions provided the following information regarding use of the product: " To Clean and Sanitize: Use wipe to pre-clean heavily soiled surfaces. No pre-cleaning is necessary for 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 wipes." There is a precautionary statement that states that the wipes are not for cleaning or sanitizing human skin.

The proposed label (7-1-02) submitted with this submission has deleted directions which include Food Service Sanitation Recommendations, as listed in original submitted label. Statement [KIMBERLY CLARK KIMTECH® PRE-MOISTENED SANITIZER WIPE] can be used in accordance wit the U.S. Public Health Service food service recommendations.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

The applicant appears to be submitting data supporting efficacy claims for both non-food contact and food contact surfaces. Efficacy studies provided in the data package were conducted to show that the product meets EPA standards for use on food-contact surfaces (i.e., DIS/TSS- 4). Tests were not conducted to show specifically that the product meets the less-stringent EPA standards for use of a product on non-food-contact surfaces (i.e., DIS/TSS-10).

Sanitizer for Use on Hard Surfaces Using Presaturated or Impregnated Towelettes (for Previously Cleaned Food-Contact Surfaces)

To substantiate sanitizing claims for treated surfaces (e.g., floors, walls, furnishings), the applicant must submit data to show that the product, when used as directed, will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in sanitizing hard surfaces. The product should be tested by wiping the test surface with the saturated towelette, and then subculturing the test surface after the specified holding time.

The towelette should be removed from its container and subsequently handled with sterile gloves. One towelette (per lot) should be used to wipe the inoculated test carriers. The area of the towelette used for wiping should be rotated so as to expose a maximum amount of its surface in the course of wiping a set of carriers. After wiping the last carrier for a particular towelette, all of the liquid remaining in the material should be expressed into an empty sterile container by squeezing the towelette; after a specified holding time (equal to the contact time stated on the product label), an aliquot from this container (ca. 0.1 mL) should be subcultured in the same manner as the carriers.

Three product samples representing three different batches, one of which is at least 60 days old, should be tested against *Escherichia coli* and *Staphylococcus aureus*. The results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to actual count and percentage reduction over control. The minimum concentration of the product which provides the results required is the minimum effective concentration. These Agency standards are presented in DIS/TSS-4, Sanitizer Rinses (for previously cleaned food-contact surfaces), the Subdivision G guidelines, and (as per the applicant) EPA/AD Method Guidance #02, "Draft Interim Guidance for AD Staff, April 12, 2001."

In addition, products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. This Agency standard is presented in DIS/TSS-2.

Label Requirements for Products for the Sanitation of Food Contact Surfaces

Directions for use must include (among other things) the following: (1) The necessity for removal of gross food particles and soil by a pre-flush, or pre-scrape and, when necessary, pre-soak treatment. (2) The contact time of at least 1 minute is required for sanitation. (3) A potable water rinse must be recommended for removal of the use solution from the food contact surfaces if the instructions do not indicate that the use solution is to be drained from the surface and the item air dried. These Agency standards are presented in DIS/TSS-17.

IV COMMENTS ON THE SUBMITTED ADDITIONAL INFORMATION

1. MRID No. 457089-01- Efficacy Performance of Expressed Liquid, Rhonda Jones, Scientific & Regulatory Consultants, Inc., Efficacy studies were independently conducted at Hill Top Research, Inc., Cincinnati, OH. This study was conducted on Kimberly-Clark KIMTECH® Pre-Moistened Sanitizer Wipe as a one-step food contact and non-food contact sanitizer towelette against *Staphylococcus aureus, Escherichia coli*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Shigella boydii*, *Klebsiella pneumoniae* and *Salmonella choleraesuis* in the presence of a 5% organic soil load on 4 square feet after 30 seconds.

Kimberly-Clark KIMTECH® Pre-Moistened Sanitizer Wipe Lot 7345-76A

Test Organism	Hill Top Report (HTR) Number MRID No.	Kimberly-Clark KIMTECH® Pre-Moistened Sanitizer Wipe		
		Sum Of Numbers Control Dishes / 4 square fee (CFU/4sq. ft.)	Sum of Survivors from the Expressed Fluid (CFU/ml Fluid)	Expressed Fluid Percent Reduction
S. aureus ATCC 6538	HTR No. 01-109358-11 MRID No. 45617106	1.2×10^8	$<1.0 \times 10^1$	>99.9999
E. coli ATCC 11229	HTR No. 01-109358-11 MRID No. 45617106	1.7×10^8	$<1.0 \times 10^1$	>99.9999
K. pneumoniae ATCC 4352	HTR No. 01-109643-11 MRID No. 45617108	2.2×10^9	$<1.0 \times 10^1$	>99.9999
E. coli O157:H7 ATCC 43895	HTR No. 01-109655-11 MRID No. 45617109	9.6×10^7	$<1.0 \times 10^1$	>99.9999
L. monocytogenes ATCC 15313	HTR No. 01-109636-11 MRID No. 45617110	1.5×10^8	$<1.0 \times 10^1$	>99.9999
L. monocytogenes ATCC 19115	HTR No. 01-109656-11 MRID No. 45617113	1.4×10^8	$<1.0 \times 10^1$	>99.9999
S. boydii ATCC 9207	HTR No. 01-109644-11 MRID No. 45617112	3.4×10^8	$<1.0 \times 10^1$	>99.9999
S. choleraesuis ATCC 10708	HTR No. 01-109359-11 MRID No. 45617111	7.5×10^7	$<1.0 \times 10^1$	>99.9999

Kimberly-Clark KIMTECH® Pre-Moistened Sanitizer Wipe Lot 7345-76B

Test Organism	Hill Top Report (HTR) Number MRID No.	Kimberly-Clark KIMTECH® Pre-Moistened Sanitizer Wipe		
		Sum Of Numbers Control Dishes / 4 square fee (CFU/4sq. ft.)	Sum of Survivors from the Expressed Fluid (CFU/ml Fluid)	Expressed Fluid Percent Reduction
S. aureus ATCC 6538	HTR No. 01-109358-11 MRID No. 45617106	1.5×10^9	$<1.0 \times 10^1$	>99.9999
E. coli ATCC 11229	HTR No. 01-109358-11 MRID No. 45617106	1.2×10^8	$<1.0 \times 10^1$	>99.9999
K. pneumoniae ATCC 4352	HTR No. 01-109643-11 MRID No. 45617108	2.4×10^9	$<1.0 \times 10^1$	>99.9999
E. coli O157:H7 ATCC 43895	HTR No. 01-109655-11 MRID No. 45617109	1.7×10^8	$<1.0 \times 10^1$	>99.9999
L. monocytogenes ATCC 15313	HTR No. 01-109636-11 MRID No. 45617110	5.9×10^8	$<1.0 \times 10^1$	>99.9999
L. monocytogenes ATCC 19115	HTR No. 01-109656-11 MRID No. 45617113	1.7×10^8	$<1.0 \times 10^1$	>99.9999
S. boydii ATCC 9207	HTR No. 01-109644-11 MRID No. 45617112	2.0×10^8	$<1.0 \times 10^1$	>99.9999
S. choleraesuis ATCC 10708	HTR No. 01-109359-11 MRID No. 45617111	1.8×10^7	$<1.0 \times 10^1$	>99.9999
S. aureus ATCC 6538	HTR No. 01-109657-11 MRID No. 45617107	3.2×10^8	$<1.0 \times 10^1$	>99.9999
E. coli ATCC 11229	HTR No. 01-109657-11 MRID No. 45617107	1.1×10^8	$<1.0 \times 10^1$	>99.9999

VI CONCLUSIONS

The submitted efficacy data/additional information (MRID No. 457089-01) appear to support the use of the product, Kimberly-Clark KIMTECH® Pre-Moistened Sanitizer Wipe as a food contact and non-food contact sanitizer towelette against *Staphylococcus aureus, Escherichia coli*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Shigella boydii*, *Klebsiella pneumoniae* and *Salmonella choleraesuis* in the presence of a 5% organic soil load on 4 square feet after 30 seconds. The average percent reduction was >99.9999 for Lot Nos. 7345-76A and 7345-76B