UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 22, 2002

MEMORANDUM:

Subject: Efficacy Review for EPA Reg. Nos.: 9402-O, "KIMTECH® PRE-MOISTENED SANITIZER WIPE"
DP Barcodes: D282049
Case No.: 071463

From: Emily Mitchell, M.S., Team Leader Emily Mitchell 6/5/02
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

To: Velma Noble, PM 31/Tracy Lantz
Regulatory Management Branch I
Antimicrobials Division (7510C)

Through: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

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%

SUMMARY OF INFORMATION REVIEWED AND FINDINGS/CONCLUSIONS:

DynCorp I&ET efficacy review has undergone secondary review by AD/PSB/EET. The contractor's review reflect EPA's Pesticide Assessment Guideline requirements and regulations and the findings/conclusions are scientifically sound. However, additional efficacy data must be submitted before approval of this product. The regulatory reviewer should draft a letter extracting the contractor's comments that apply with exceptions to the "RECOMMENDATIONS." Under "RECOMMENDATIONS", the comments should read as follows:

1. The efficacy data submitted for *Staphylococcus aureus* (ATCC 6538), *Escherichia coli* o157:H7(ATCC 43895), *Klebsiella pneumoniae* (ATCC 4352), *Listeria monocytogenes* (ATCC 15313), *Listeria monocytogenes* (ATCC 19115), *Salmonella choleraesuis* (ATCC 10708), *Shigella boydii* (ATCC 9207) and *Escherichia coli* (ATCC 11229) in MRID Nos. 456171-06 thru 456171-13 appear to be acceptable. Although, the results of the microorganisms surviving in the expressed liquid after exposure to the test product are provided, the percent reduction compared to the numbers control was not calculated. According to the Agency's requirements, the percent reduction should be calculated and be at least 99.999% in both the carrier and the expressed liquid subcultures.

2. The proposed label claims are not acceptable regarding the use of the product as a sanitizer on non-food contact surfaces for a 30 second contact time. The proposed label should be revised to indicate that "treated surfaces must remain wet for 60 seconds to achieve sanitization". A contact time of 60 seconds (30 seconds of wiping plus an additional 30-second exposure time) was used in each testing scenario.

3. Additionally, the label claims are not acceptable for use of the product as a sanitizer on food contact surfaces for an unspecified contact time ("until surface is thoroughly wet"). The proposed label should be revised to state a contact time of at least 1 minute, which is required by DIS/TSS-17 for food contact surface sanitizers.

4. The statements on page 2 "Tested under the tough, stringent EPA Food Contact Surface Sanitizer Wipe Standard", "Meets EPA's stringent, tough standard for food contact sanitizer wipes, "Passes the EPA's stringent, tough biocidal test for food contact sanitizer wipes, and "Effectiveness demonstrated using the stringent, tough EPA Food Contact Sanitizer Wipe standard must be deleted from label. Claims or statements expressing or implying a higher level of antimicrobial activity than other products are not acceptable. Also any other comparative or marketing claims in general, even if qualified are not acceptable.

5. The statement "For use on all hard non-porous food contact surfaces" must be revised to "For use on hard non-porous food contact surfaces (e.g. glass)"

Since the rough plastic surfaces were not tested for efficacy, your label statement can not encompass all hard non-porous surfaces.

6. On page 3, terms relating to helps stop and reduces risk of food related illness and food poisoning must be deleted from the label. Statements or claims that suggest or imply that the product can or will prevent or control disease or offer health protection are not acceptable.

7. On page 3, claims implying a healthier environment must be deleted from the label.

8. On page 3, claims such as assists in efforts to protect the nation's food supply must be deleted from the label. Statements or claims that suggest or imply that the product can or will prevent or control disease or offer health protection are not acceptable.

9. On page 4, groceries must deleted from use sites.

10. On page 4, cutting surfaces must be identified.

11. On page 5, the type of railings must be identified.

12. Playpens and cribs must be deleted from label.

13. On page 6, statements such as assures proper dilution and stop messy diluting are not appropriate statements since the product is not diluted.

14. On page 7, revise statement [reduces, halts, and aids] in cross contamination between surfaces and foods] to [reduces, halts, and aids in cross contamination of treated surfaces.]

NOTE TO PM: A copy of DynCorp I&ET Efficacy Evaluation Report dated May 20, 2002 is appended to our memorandum. Our secondary review projects Findings/Conclusions to assist regulatory in communicating the Agency's decisions to the applicant.

MEMORANDUM

DATE: May 20, 2002

SUBJECT: Efficacy Review for KIMTECH ® Pre-Moistened Sanitizer Wipe, EPA Reg. No. 009402-O; DP Barcode: D282049

FROM: DynCorp I&ET

THRU: Ian Blackwell
Antimicrobials Division

TO: Emily Mitchell
Antimicrobials Division

APPLICANT: Kimberly-Clark Corporation
Roswell, Georgia

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 non-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 eight studies (MRID Nos. 456171-06 through 456171-13), Statements of No Data Confidentiality Claims for all eight MRIDs, 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 and EPA's draft guidance entitled "Non-Residual Sanitization of Hard Inanimate Food-Contact Surfaces Using Pre-Saturated Towelettes" (April 12, 2001). DynCorp does not have a copy of the April 12, 2001 guidance; however, DynCorp does have access to other EPA guidance (undated) regarding Agency efficacy requirements for pre-saturated towelettes, which is assumed to be similar.

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 30 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 also includes Food Service Sanitation Recommendations, as follows:

"Cleaning and Sanitizing: Equipment and utensils shall be thoroughly pre-flushed or pre-scraped and when necessary, pre-soaked to remove gross food particles and soil.

1. Thoroughly wash equipment and utensils in hot detergent solution.
2. Rinse utensils and equipment thoroughly with clean water.
3. Sanitize equipment and utensils by immersion in an EPA-registered liquid sanitizer for at least 60 seconds at a temperature of 75°F.
4. For food or non-food contact surfaces and equipment too large to sanitize by immersion, apply [KIMBERLY CLARK KIMTECH PRE-MOISTENED SANITIZER WIPE] until surface is thoroughly wet.
5. Allow sanitized surface to drain and air dry."

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 EFFICACY STUDIES

1. MRID 456171-06 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, One Step Cleaner Sanitizer" for KIMTECH Pre-moistened Sanitizing Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – January 16, 2002.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11229) with 5% organic soil load (fetal bovine serum). Two lots (Lot Nos. 7345-76A and 7345-76B) of the product were tested using the Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Ed., 1995, Section 6.3.03 with modifications. Four (4) carriers of pre-sterilized glass baking dishes were inoculated with ~2.8 x 10^7 CFU/carrier (1 sq. ft.) each of the test bacteria. All four of the carriers were wiped for 30 seconds at 23±1°C with the same wipe. [A total of four glass

baking dishes were inoculated to represent a wiped surface area of four square feet.] After 30 seconds of exposure to the product after wiping, the carriers were then neutralized with AOAC Neutralizer Blanks with Sea Sand, and the surviving bacteria enumerated by the Pour Plate Method using Tryptone Glucose Extract Agar with 25 mL/L AOAC Stock Neutralizer. The plates were incubated at 35±2°C for 48±2 hours. Expressed fluid was collected from the wipes immediately after wiping; the expressed fluid from the wipes was tested in the same medium and at the same incubation times as used for the carriers. The percent reduction was calculated using the inoculated "Numbers Control" and the number of surviving organisms. Controls included: numbers control, sterility, viability, neutralizer toxicity, and neutralizer effectiveness. Neutralizer effectiveness was performed according to the following publication: Chambers, Cecil W. *A procedure for evaluating the efficiency of bactericidal agents*, J. Milk and Food Technology. Vol. 19 No. 7, 1956.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

2. MRID 456171-07 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, One Step Cleaner Sanitizer-60 Day Stability Study" for KIMTECH Pre-moistened Sanitizer Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – January 18, 2002.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11229) with 5% organic soil load (fetal bovine serum). One lot of the test substance (Lot No. 7345-75B; representing a 60-day old lot at time of testing) was tested using the Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Ed., 1995, Section 6.3.03 with modifications. Four (4) carriers of pre-sterilized glass baking dishes were inoculated with ~2.8 x 10^7 CFU/carrier (1 sq. ft.) each of the test bacteria. All four of the carriers were wiped for 30 seconds at 23±1°C with the same wipe. [A total of four glass baking dishes were inoculated to represent a wiped surface area of four square feet.] After 30 seconds of exposure to the product after wiping, the carriers were then neutralized with AOAC Neutralizer Blanks with Sea Sand, and the surviving bacteria enumerated by the Pour Plate Method using Tryptone Glucose Extract Agar with 25 mL/L AOAC Stock Neutralizer. The plates were incubated at 35±2°C for 48±2 hours. Expressed fluid was collected from the wipes immediately after wiping; the expressed fluid from the wipes was tested in the same medium and at the same incubation times as used for the carriers. The percent reduction was calculated using the inoculated "Numbers Control" and number of surviving organisms. Controls included: numbers control, sterility, viability, and neutralizer effectiveness. Neutralizer effectiveness was performed according the following publication: Chambers, Cecil W. *A procedure for evaluating the efficiency of bactericidal agents*, J. Milk and Food Technology. Vol. 19 No. 7, 1956.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

3. MRID 456171-08 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, One Step Cleaner Sanitizer" for KIMTECH Pre-moistened Sanitizing Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – January 17, 2002.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352) with 5% organic soil load (fetal bovine serum). Two lots (Lot Nos. 7345-76A and 7345-76B) of the product were tested using the Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Ed., 1995, Section 6.3.03 with modifications. Four (4) carriers of pre-sterilized glass baking dishes were inoculated with ~2.8 x 10^7 CFU/carrier (1 sq. ft.) each of the test bacteria. All four of the carriers were wiped for 30 seconds at 23±1°C with the same wipe. [A total of four glass baking dishes were inoculated to represent a wiped surface area of four square feet.] After 30 seconds of exposure to the product after wiping, the carriers were then neutralized with AOAC Neutralizer Blanks with Sea Sand, and the surviving bacteria enumerated by the Pour Plate Method using Tryptone Glucose Extract Agar with 25 mL/L AOAC Stock Neutralizer. The plates were incubated at 35±2°C for 48±2 hours. Expressed fluid was collected from the wipes immediately after wiping; the expressed fluid from the wipes was tested in the same medium and at the same incubation times as used for the carriers. The percent reduction was calculated using the inoculated "Numbers Control". Controls included: numbers control, sterility, viability, and neutralizer effectiveness. Neutralizer effectiveness was performed according the following publication: Chambers, Cecil W. *A procedure for evaluating the efficiency of bactericidal agents*, J. Milk and Food Technology. Vol. 19 No. 7, 1956.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

4. MRID 456171-09 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, One Step Cleaner Sanitizer" for KIMTECH Pre-moistened Sanitizing Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – January 17, 2002.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 43895) with 5% organic soil load (fetal bovine serum). Two lots (Lot Nos. 7345-76A and 7345-76B) of the product were tested using the Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Ed., 1995, Section 6.3.03 with modifications. Four (4) carriers of pre-sterilized glass baking dishes were inoculated with ~2.8 x 10^7 CFU/carrier (1 sq. ft.) each of the test bacteria. All four of the carriers were wiped for 30 seconds at 23±1°C with the same wipe. [A total of four glass baking dishes were inoculated to represent a wiped surface area of four square feet.] After 30 seconds of exposure to the product after wiping, the carriers were then neutralized with AOAC Neutralizer Blanks with Sea Sand, and the surviving bacteria enumerated by the Pour Plate Method using Tryptone Glucose Extract Agar with 25 mL/L AOAC Stock Neutralizer. The plates were incubated at 35±2°C for 48±2 hours. Expressed fluid was collected from the wipes immediately after wiping; the expressed fluid from the wipes was tested in the same medium and at the same incubation times as used for the carriers. The percent reduction was calculated using the inoculated "Numbers Control".

Controls included: numbers control, sterility, viability, and neutralizer effectiveness. Neutralizer effectiveness was performed according the following publication: Chambers, Cecil W. *A procedure for evaluating the efficiency of bactericidal agents*, J. Milk and Food Technology. Vol. 19 No. 7, 1956.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

5. MRID 456171-10 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, One Step Cleaner Sanitizer" for KIMTECH Pre-moistened Sanitizing Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – January 16, 2002.

This study was conducted against *Listeria monocytogenes* (ATCC 15313) with 5% organic soil load (fetal bovine serum). Two lots (Lot Nos. 7345-76A and 7345-76B) of the product were tested using the Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Ed., 1995, Section 6.3.03 with modifications. Four (4) carriers of pre-sterilized glass baking dishes were inoculated with ~2.8 x 10^7 CFU/carrier (1 sq. ft.) each of the test bacteria. All four of the carriers were wiped for 30 seconds at 23±1°C with the same wipe. [A total of four glass baking dishes were inoculated to represent a wiped surface area of four square feet.] After 30 seconds of exposure to the product after wiping, the carriers were then neutralized with AOAC Neutralizer Blanks with Sea Sand, and the surviving bacteria enumerated by the Pour Plate Method using Brain Heart Infusion Agar with 25 mL/L AOAC Stock Neutralizer. The plates were incubated at 35±2°C for 48±2 hours. Expressed fluid was collected from the wipes immediately after wiping; the expressed fluid from the wipes was tested in the same medium and at the same incubation times as used for the carriers. The percent reduction was calculated using the inoculated "Numbers Control". Controls included: numbers control, sterility, viability, and neutralizer effectiveness. Neutralizer effectiveness was performed according the following publication: Chambers, Cecil W. *A procedure for evaluating the efficiency of bactericidal agents*, J. Milk and Food Technology. Vol. 19 No. 7, 1956.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

6. MRID 456171-11 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, One Step Cleaner Sanitizer" for KIMTECH Pre-moistened Sanitizing Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – January 16, 2002.

This study was conducted against *Salmonella choleraesuis* (ATCC 10708) with 5% organic soil load (fetal bovine serum). Two lots (Lot Nos. 7345-76A and 7345-76B) of the product were tested using the Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Ed., 1995, Section 6.3.03 with modifications. Four (4) carriers of pre-sterilized glass baking dishes were inoculated with ~2.8 x 10^7 CFU/carrier (1 sq. ft.) each of the test bacteria. All four of the carriers were wiped for

30 seconds at 23±1°C with the same wipe. [A total of four glass baking dishes were inoculated to represent a wiped surface area of four square feet.] After 30 seconds of exposure to the product after wiping, the carriers were then neutralized with AOAC Neutralizer Blanks with Sea Sand, and the surviving bacteria enumerated by the Pour Plate Method using Tryptone Glucose Extract Agar with 25 mL/L AOAC Stock Neutralizer. The plates were incubated at 35±2°C for 48±2 hours. Expressed fluid was collected from the wipes immediately after wiping; the expressed fluid from the wipes was tested in the same medium and incubation times as used for the carriers. The percent reduction was calculated using the inoculated "Numbers Control". Controls included: numbers control, sterility, viability, and neutralizer effectiveness. Neutralizer effectiveness was performed according the following publication: Chambers, Cecil W. *A procedure for evaluating the efficiency of bactericidal agents*, J. Milk and Food Technology. Vol. 19 No. 7, 1956.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

7. MRID 456171-12 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, One Step Cleaner Sanitizer" for KIMTECH Pre-moistened Sanitizing Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – January 17, 2002.

This study was conducted against *Shigella boydii* (ATCC 9207) with 5% organic soil load (fetal bovine serum). Two lots (Lot Nos. 7345-76A and 7345-76B) of the product were tested using the Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Ed., 1995, Section 6.3.03 with modifications. Four (4) carriers of pre-sterilized glass baking dishes were inoculated with ~2.8 x 10^7 CFU/carrier (1 sq. ft.) each of the test bacteria. All four of the carriers were wiped for 30 seconds at 23±1°C with the same wipe. [A total of four glass baking dishes were inoculated to represent a wiped surface area of four square feet.] After 30 seconds of exposure to the product after wiping, the carriers were then neutralized with AOAC Neutralizer Blanks with Sea Sand, and the surviving bacteria enumerated by the Pour Plate Method using Tryptone Glucose Extract Agar with 25 mL/L AOAC Stock Neutralizer. The plates were incubated at 35±2°C for 48±2 hours. Expressed fluid was collected from the wipes immediately after wiping; the expressed fluid from the wipes was tested in the same medium and at the same incubation times as used for the carriers. The percent reduction was calculated using the inoculated "Numbers Control". Controls included: numbers control, sterility, viability, and neutralizer effectiveness. Neutralizer effectiveness was performed according the following publication: Chambers, Cecil W. *A procedure for evaluating the efficiency of bactericidal agents*, J. Milk and Food Technology. Vol. 19 No. 7, 1956.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

8. MRID 456171-13 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants, One Step Cleaner Sanitizer" for KIMTECH Pre-moistened Sanitizing Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – January 18, 2002.

This study was conducted against *Listeria monocytogenes* (ATCC 19115) with 5% organic soil load (fetal bovine serum). Two lots (Lot Nos. 7345-76A and 7345-76B) of the product were tested using the Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 16th Ed., 1995, Section 6.3.03 with modifications. Four (4) carriers of pre-sterilized glass baking dishes were inoculated with ~2.8 x 10^7 CFU/carrier (1 sq. ft.) each of the test bacteria. All four of the carriers were wiped for 30 seconds at 23±1°C with the same wipe. [A total of four glass baking dishes were inoculated to represent a wiped surface area of four square feet.] After 30 seconds of exposure to the product after wiping, the carriers were then neutralized with AOAC Neutralizer Blanks with Sea Sand, and the surviving bacteria enumerated by the Pour Plate Method using Brain Heart Infusion Agar with 25 mL/L AOAC Stock Neutralizer. The plates were incubated at 35±2°C for 48±2 hours. Expressed fluid was collected from the wipes immediately after wiping; the expressed fluid from the wipes was tested in the same medium and at the same incubation times as used for the carriers. The percent reduction was calculated using the inoculated "Numbers Control". Controls included: numbers control, sterility, viability, and neutralizer effectiveness. Neutralizer effectiveness was performed according the following publication: Chambers, Cecil W. *A procedure for evaluating the efficiency of bactericidal agents*, J. Milk and Food Technology. Vol. 19 No. 7, 1956.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

V RESULTS

MRID Number	Organism		Lot No. 7345-76A	Lot No. 7345-76B
456171-06	*Staphylococcus aureus*	1 sq. ft.	>99.9999% average reduction	>99.9999% average reduction
		4 sq. ft.	>99.9999% reduction	>99.9999% reduction
		Expressed Liquid	<1.0 x 10^1 CFU/mL of fluid in wipe	<1.0 x 10^1 CFU/mL of fluid in wipe
	Escherichia coli	1 sq. ft.	>99.9999% average reduction	>99.9999% average reduction
		4 sq. ft.	>99.9999% reduction	>99.9999% reduction
		Expressed Liquid	<1.0 x 10^1 CFU/mL of fluid in wipe	<1.0 x 10^1 CFU/mL of fluid in wipe

MRID Number	Organism		Lot No. 7345-75B
456171-07	*Staphylococcus aureus*	1 sq. ft.	>99.9998% average reduction
		4 sq. ft.	>99.9998% reduction
		Expressed Liquid	<1.0 x 10^1 CFU/mL of fluid in wipe
	Escherichia coli	1 sq. ft.	>99.9999% average reduction
		4 sq. ft.	>99.9999% reduction
		Expressed Liquid	<1.0 x 10^1 CFU/mL of fluid in wipe

MRID Number	Organism		Lot No. 7345-76A	Lot No. 7345-76B
456171-08	*Klebsiella pneumoniae*	1 sq. ft.	>99.9999% average reduction	>99.9999% average reduction
		4 sq. ft.	>99.9999% reduction	>99.9999% reduction
		Expressed Liquid	<1.0 x 10^1 CFU/mL of fluid in wipe	<1.0 x 10^1 CFU/mL of fluid in wipe
456171-09	*Escherichia coli* O157:H7	1 sq. ft.	>99.9999% average reduction	>99.9999% average reduction
		4 sq. ft.	>99.9999% reduction	>99.9999% reduction
		Expressed Liquid	<1.0 x 10^1 CFU/mL of fluid in wipe	<1.0 x 10^1 CFU/mL of fluid in wipe
456171-10	*Listeria monocytogenes* (ATCC 15313)	1 sq. ft.	>99.9998% average reduction	99.9998% average reduction
		4 sq. ft.	>99.9998% reduction	99.9998% reduction
		Expressed Liquid	<1.0 x 10^1 CFU/mL of fluid in wipe	2.0 x 10^1 CFU/mL of fluid in wipe
456171-11	*Salmonella choleraesuis*	1 sq. ft.	>99.9998% average reduction	>99.9999% average reduction
		4 sq. ft.	>99.9998% reduction	>99.9999% reduction
		Expressed Liquid	<1.0 x 10^1 CFU/mL of fluid in wipe	<1.0 x 10^1 CFU/mL of fluid in wipe
456171-12	*Shigella boydii*	1 sq. ft.	>99.9999% average reduction	>99.9999% average reduction

MRID Number	Organism		Lot No. 7345-76A	Lot No. 7345-76B
		4 sq. ft.	>99.9999% reduction	>99.9999% reduction
		Expressed Liquid	<1.0 x 10^1 CFU/mL of fluid in wipe	<1.0 x 10^1 CFU/mL of fluid in wipe
456171-13	*Listeria monocytogenes* (ATCC 19115)	1 sq. ft.	>99.9999% average reduction	>99.9997% average reduction
		4 sq. ft.	>99.9999% reduction	>99.9998% reduction
		Expressed Liquid	<1.0 x 10^1 CFU/mL of fluid in wipe	<1.0 x 10^1 CFU/mL of fluid in wipe

VI CONCLUSIONS

1. The submitted efficacy data (MRID Nos. 456171-06 and 456171-07) appear to support the use of the product, KIMTECH Pre-moistened Sanitizer Wipe, as a sanitizer with bactericidal activity when tested against *Staphylococcus aureus* and *Escherichia coli* in the presence of a 5% organic soil load (fetal bovine serum) on hard surfaces using a wiping time of 30 seconds and an exposure period of 30 seconds. The average percent reduction was >99.9999 for *Escherichia coli* for the three product lots tested, one of which was at least 60 days old. For *Staphylococcus aureus,* the average percent reduction was >99.9999 for Lot Nos. 7345-76A and 7345-76B and >99.9998 for Lot No. 7345-75B.

Discussion of Controls: The control results were as follows:

For *Staphylococcus aureus* (Lot No. 7345-76A):

Average count of the numbers control	3.0 x 10^7 CFU/1 sq. ft. and 1.2 x 10^8 CFU/4 sq. ft.
Count of the surviving organisms	<2.0 x 10^1 CFU/1 sq. ft. for three replicates and <5.0 x 10^1 CFU/1 sq. ft. for one replicate

For *Staphylococcus aureus* (Lot No. 7345-76B):

Average count of the numbers control	3.8 x 10^8 CFU/1 sq. ft. and 1.5 x 10^9 CFU/4 sq. ft.
Count of the surviving organisms	<2.0 x 10^1 CFU/1 sq. ft. for two replicates, 4.0 x 10^1 CFU/1 sq. ft. for one replicate, and 3.1 x 10^2/1 CFU/1 sq. ft. for one replicate

For *Escherichia coli* (Lot No. 7345-76A):

Average count of the numbers control	4.2 x 10^7 CFU/1 sq. ft. and 1.7 x 10^8 CFU/4 sq. ft.

Count of the surviving organisms	<2.0 x 10^1 CFU/1 sq. ft. for all four replicates

For *Escherichia coli* (Lot No. 7345-76B):

Average count of the numbers control	3.0 x 10^7 CFU/1 sq. ft. and 1.2 x 10^8 CFU/4 sq. ft.
Count of the surviving organisms	<2.0 x 10^1 CFU/1 sq. ft. for three replicates and <3.0 x 10^1/1 sq. ft. for one replicate

For *Staphylococcus aureus* (Lot No. 7345-75B):

Average count of the numbers control	7.9 x 10^7 CFU/1 sq. ft. and 3.2 x 10^8 CFU/4 sq. ft.
Count of the surviving organisms	<2.0 x 10^1 CFU/1 sq. ft. for two replicates, 4.0 x 10^2 CFU/1 sq. ft. for one replicate, and <3.0 x 10^1 CFU/1 sq. ft. for one replicate

For *Escherichia coli* (Lot No. 7345-75B):

Average count of the numbers control	2.8 x 10^7 CFU/1 sq. ft. and 1.1 x 10^8 CFU/4 sq. ft.
Count of the surviving organisms	<2.0 x 10^1 CFU/1 sq. ft. for two replicates, <4.0 x 10^1 CFU/1 sq. ft. for one replicate, and 7.0 x 10^1 CFU/1 sq. ft. for one replicate

The count of both surviving microorganisms in the expressed liquid was reported on page 12 of both studies as <1.0 x 10^1 CFU/mL of fluid in wipe. The applicant failed to include the percent reduction of the microorganism in the expressed liquid. The neutralizer was found to be effective as a neutralizer and not toxic to either *Escherichia coli* or *Staphylococcus aureus*. The applicant failed to submit the results of the sterility and viability controls.

2. The submitted efficacy data (MRID 456171-08) appear to support the use of the product, KIMTECH Pre-moistened Sanitizer Wipe, as a sanitizer with bactericidal activity when tested against *Klebsiella pneumoniae* in the presence of a 5% organic soil load (fetal bovine serum) on hard surfaces using a wiping time of 30 seconds and an exposure period of 30 seconds. The average percent reduction was >99.9999.

Discussion of Controls: The control results were as follows:

For *Klebsiella Pneumoniae* (Lot No. 7345-76A):

Average count of the numbers control	5.6 x 10^8 CFU/1 sq. ft. and 2.2 x 10^9 CFU/4 sq. ft.
Count of the surviving organisms	<2.0 x 10^1 CFU/1 sq. ft. for one replicate, 3.3 x 10^2 CFU/1 sq. ft. for one replicate, 4.0 x 10^1 CFU/1 sq. ft. for one replicate, and 5.7x 10^2 CFU/1 sq. ft. for one replicate

For *Klebsiella Pneumoniae* (Lot No. 7345-76B):

Average count of the numbers control	6.1×10^7 CFU/1 sq. ft. and 2.4×10^8 CFU/4 sq. ft.
Count of the surviving organisms	$<2.0 \times 10^1$ CFU/1 sq. ft. for two replicates, 1.1×10^2 CFU/1 sq. ft. for one replicate, and $<6.0 \times 10^1$ CFU/1 sq. ft. for one replicate

The neutralizer was found to be effective as a neutralizer and not toxic to the test organism. The applicant failed to submit the results of the sterility and viability controls.

3. The submitted efficacy data (MRID 456171-09) appear to support the use of the product, KIMTECH Pre-moistened Sanitizer Wipe, as a sanitizer with bactericidal activity when tested against *Escherichia coli* O157:H7 in the presence of a 5% organic soil load (fetal bovine serum) on hard surfaces using a wiping time of 30 seconds and an exposure period of 30 seconds. The average percent reduction was >99.9999.

Discussion of Controls: The control results were as follows:

For *Escherichia coli* O157:H7 (Lot No. 7345-76A):

Average count of the numbers control	2.4×10^7 CFU/1 sq. ft. and 9.6×10^7 CFU/4 sq. ft.
Count of the surviving organisms	$<2.0 \times 10^1$ CFU/1 sq. ft. for all four replicates

For *Escherichia coli* O157:H7 (Lot No. 7345-76B):

Average count of the numbers control	4.4×10^7 CFU/1 sq. ft. and 1.7×10^8 CFU/4 sq. ft.
Count of the surviving organisms	$<2.0 \times 10^1$ CFU/1 sq. ft. for three replicates and $<3.0 \times 10^1$ CFU/1 sq. ft. for one replicate

The neutralizer was found to be effective as a neutralizer and not toxic to the test organism. The applicant failed to submit the results of the sterility and viability controls.

4. The submitted efficacy data (MRID 456171-10) appear to support the use of the product, KIMTECH Pre-moistened Sanitizer Wipe, as a sanitizer with bactericidal activity when tested against *Listeria monocytogenes* in the presence of 5% organic soil load (fetal bovine serum) on hard surfaces using a wiping time of 30 seconds and an exposure period of 30 seconds. The average percent reduction was 99.9998.

Discussion of Controls: The control results were as follows:

For *Listeria monocytogenes* (Lot No. 7345-76A):

Average count of the numbers control	3.7×10^7 CFU/1 sq. ft. and 1.5×10^8 CFU/4 sq. ft.

Count of the surviving organisms	<2.0 x 10^1 CFU/1 sq. ft. for one replicate, <3.0 x 10^1 CFU/1 sq. ft. for one replicate, <4.0 x 10^1 CFU/1 sq. ft. for one replicate, and 2.2 x 10^2 CFU/1 sq. ft. for one replicate

For *Listeria monocytogenes* (Lot No. 7345-76B):

Average count of the numbers control	1.5 x 10^8 CFU/1 sq. ft. and 5.9 x 10^8 CFU/4 sq. ft.
Count of the surviving organisms	1.1 x 10^2 CFU/1 sq. ft. for one replicate, 1.7 x 10^2 CFU/1 sq. ft. for one replicate, 2.0 x 10^2 CFU/1 sq. ft. for one replicate and 7.4 x 10^2 CFU/1 sq. ft. for one replicate

The neutralizer was found to be effective as a neutralizer and not toxic to the test organism. The applicant failed to submit the results of the sterility and viability controls.

5. The submitted efficacy data (MRID 456171-11) appear to support the use of the product, KIMTECH Pre-moistened Sanitizer Wipe, as a sanitizer with bactericidal activity when tested against *Salmonella choleraesuis* in the presence of a 5% organic soil load (fetal bovine serum) on hard surfaces using a wiping time of 30 seconds and an exposure period of 30 seconds. The average percent reduction was >99.9998 for Lot No. 7345-76A and the average percent reduction was > 99.9999 for Lot No. 7345-76B.

Discussion of Controls: The control results were as follows:

For *Salmonella choleraesuis* (Lot No. 7345-76A):

Average count of the numbers control	1.9 x 10^7 CFU/1 sq. ft. and 7.5 x 10^7 CFU/4 sq. ft.
Count of the surviving organisms	<3.0 x 10^1 CFU/1 sq. ft. for two replicates, <4.0 x 10^1 CFU/1 sq. ft. for one replicate, and 4.0 x 10^1 CFU/1 sq. ft. for one replicate

For *Salmonella choleraesuis* (Lot No. 7345-76B):

Average count of the numbers control	4.6 x 10^7 CFU/1 sq. ft. and 1.8 x 10^8 CFU/4 sq. ft.
Count of the surviving organisms	<2.0 x 10^1 CFU/1 sq. ft.

The neutralizer was found to be effective as a neutralizer and not toxic to the test organism. The applicant failed to submit the results of the sterility and viability controls.

6. The submitted efficacy data (MRID 456171-12) appear to support the use of the product, KIMTECH Pre-moistened Sanitizer Wipe, as a sanitizer with bactericidal activity when tested against *Shigella boydii* in the presence of a 5% organic soil load (fetal bovine serum) on hard surfaces using a wiping time of 30 seconds and an exposure period of 30 seconds. The average percent reduction was > 99.9999.

Discussion of Controls: The control results were as follows:

For *Shigella boydii* (Lot No. 7345-76A):

Average count of the numbers control	8.6×10^7 CFU/1 sq. ft. and 3.4×10^8 CFU/4 sq. ft.
Count of the surviving organisms	$<2.0 \times 10^1$ CFU/1 sq. ft. for three replicates and $<3.0 \times 10^1$ CFU/1 sq. ft. for one replicate

For *Shigella boydii* (Lot No. 7345-76B):

Average count of the numbers control	5.0×10^7 CFU/1 sq. ft. and 2.0×10^8 CFU/4 sq. ft.
Count of the surviving organisms	$<2.0 \times 10^1$ CFU/1 sq. ft. for two replicates, $<3.0 \times 10^1$ CFU/1 sq. ft. for one replicate, and $<4.0 \times 10^1$ CFU/1 sq. ft. for one replicate

The neutralizer was found to be effective as a neutralizer and not toxic to the test organism. The applicant failed to submit the results of the sterility and viability controls.

7. The submitted efficacy data (MRID 456171-13) appear to support the use of the product, KIMTECH Pre-moistened Sanitizer Wipe, as a sanitizer with bactericidal activity when tested against *Listeria monocytogenes* in the presence of 5% organic soil load (fetal bovine serum) on hard surfaces using a wiping time of 30 seconds and an exposure period of 30 seconds. The average percent reduction was >99.9999 for Lot No. 7345-76A and the average percent reduction was at least >99.9997 for Lot No. 7345-76B.

Discussion of Controls: The control results were as follows:

For *Listeria monocytogenes* (Lot No. 7345-76A):

Average count of numbers control	3.5×10^7 CFU/1 sq. ft. and 1.4×10^8 CFU/4 sq. ft.
Count of surviving organisms	$<2.0 \times 10^1$ CFU/1 sq. ft. for three replicates and 6.0×10^1 CFU/1 sq. ft. for one replicate

For *Listeria monocytogenes* (Lot No. 7345-76B):

Average count of numbers control	4.2×10^7 CFU/1 sq. ft. and 1.7×10^8 CFU/4 sq. ft.
Count of surviving organisms	$<2.0 \times 10^1$ CFU/1 sq. ft. for one replicate, $<4.0 \times 10^1$ CFU/1 sq. ft. for one replicate, 1.5×10^2 CFU/1 sq. ft. for one replicate, and 2.0×10^2 CFU/1 sq. ft. for one replicate

The neutralizer was found to be effective as a neutralizer and not toxic to the test organism. The applicant failed to submit the results of the sterility and viability controls.

VII RECOMMENDATIONS

1. The label claims (as supported by MRID Nos. 456171-06 through 456171-13) are acceptable with correction (related to contact times) regarding the use of the product as a sanitizer in the presence of 5% organic soil (fetal bovine serum) on hard surfaces for the following organisms:

Escherichia coli (ATCC 11229)	(MRIDs 456171-06 and 456171-07)
Escherichia coli O157:H7 (ATCC 43895)	(MRID 456171-09)
Klebsiella pneumoniae (ATCC 4352)	(MRID 456171-08)
Listeria monocytogenes (ATCC 15313)	(MRID 456171-10)
Listeria monocytogenes (ATCC 19115)	(MRID 456171-13)
Salmonella choleraesuis (ATCC 10708)	(MRID 456171-11)
Shigella boydii (ATCC 9207)	(MRID 456171-12)
Staphylococcus aureus (ATCC 6538)	(MRIDs 456171-06 and 456171-07)

The proposed label claims (as supported by MRID Nos. 456171-06 through 456171-13) are <u>not</u> acceptable regarding the use of the product as a sanitizer <u>on non-food contact surfaces</u> for a 30-second contact time. Prior to approving the proposed label, the Agency needs to request that the applicant revise the proposed label to indicate that "treated surfaces must remain wet for 60 seconds to achieve sanitization." A contact time of 60 seconds (30 seconds of wiping plus an additional 30-second exposure time) was used in each MRID.

Additionally, the label claims (as supported by MRID Nos. 456171-06 through 456171-13) are <u>not</u> acceptable regarding the use of the product as a sanitizer <u>on food contact surfaces</u> for an unspecified contact time ("until surface is thoroughly wet"). Prior to approving the proposed label, the Agency needs to request that the applicant revise the proposed label to indicate that contact time of at least 1 minute (60 seconds), which is required by DIS/TSS-17 for food contact surface sanitizers.

Prior to approving the proposed label (with the contact times corrected), the Agency may want to request that the percent reduction of the microorganisms in the expressed liquid tests be calculated and submitted for review. Although the results of the microorganisms surviving in the expressed liquid after exposure to the test product are provided, the percent reduction compared to the numbers control was not calculated. According to EPA requirements, the percent reduction should be calculated and be at least 99.999% in both the carrier and the expressed liquid subcultures. The Agency may also request that the applicant submit the results for the sterility and viability controls.