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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

June 4, 2003

MEMORANDUM:

Subject: Efficacy Review EPA Reg. No. 9402-9 *Kimtech Pre-Moistened Sanitizer Wipes*
DP Barcode 288658
Case No. 071463

From: Nancy Whyte, Microbiologist NGW
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To: Velma Noble/Tracy Lantz
Regulatory Management Branch I
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Thru: Emily Mitchell, M.S., Team Leader Emily Mitchell 7/22/03
Efficacy Evaluation Team
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Thru: Michele E. Wingfield, Chief
Product Science Branch
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Applicant: Kimberly-Clark Corp.
1400 Holcomb Bridge Road
Roswell, Georgia 30076

Formulation Label:

Active Ingredient(s)	**%wt.**
n-Alkyl (50% C_{14}, 40% C_{12}, 10% C_{16}) dimethyl dimethyl benzyl ammonium chloride	0.0160%
Octyl decyl dimethyl ammonium chloride	0.0120%
Didecyl dimethyl ammonium chloride	0.0072%
Dioctyl dimethyl ammonium chloride	0.0048%
Inert ingredients	99.9600%
Total	100.000%

Hy[illegible] 3500

Background:

The product, *KIMTECH® Pre-Moistened Sanitizer Wipe* (EPA Reg. No. 9402-9), is an EPA-approved sanitizer for use on hard, non-porous, food contact surfaces in establishments such as restaurants; institutional, hospital, and school kitchens; and grocery stores; and non-food contact surfaces at work and home. The applicant submitted studies to satisfy a conditional registration requirement, which was required by the Registration Notice for this product, dated August 7, 2002. Specifically, EPA required that the applicant submit certain efficacy data using a rough plastic surface. All studies were conducted at Hill Top Research, Inc. located at Main and Mill Streets, Miamiville, OH 45147.

This data package contained correspondence from the applicant, dated February 3, 2003; EPA's February 12, 2003 Report of Analysis for Compliance with PR Notice 86-5; EPA Form 8570-4 (Confidential Statement of Formula); seven studies (MRID Nos. 458633-01 through 458633-07); Statements of No Data Confidentiality Claims for all studies; and the last accepted label dated February 3, 2003

II. Use Directions:

The towelette product is designed for use as a sanitizer on hard, non-porous, non-food contact surfaces such as sinks, faucets, toilet seats and rims, towel dispensers, hand railings, infant changing tables, stall doors, bathtubs and showers, hampers, tiled walls, telephones, diaper pails, and door knobs. The towelette product is also designed for use as a sanitizer on hard, non-porous, food contact surfaces such as tables, chairs, grocery store carts, food trays, non-wood cutting boards, microwaves, stove tops, appliances, and counters. Directions on the approved label, dated February 3, 2003 provided the following information regarding preparation and use of the product as a sanitizing wipe: Pre-clean surfaces by removing visible soil. Use a wipe to sanitize 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. For heavily soiled surfaces, use a wipe to pre-clean and remove heavy soil and then use a second wipe to sanitize.

III. Agency Standards for Proposed Change

Non-Residual Sanitization of Hard Inanimate Food-Contact Surfaces Using Pre-Saturated, Single Use Towelettes

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 standard test methods available (e.g., AOAC Germicidal Spray Products Test, AOAC Germicidal and Detergent Sanitizing Action Method), if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a simulated-use test be conducted by modifying the AOAC Germicidal Spray Products Test against *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11229) on two carrier surfaces: (1) stainless steel or glass, and (2) plastic with a rough surface (i.e., plastic cutting board). Inoculated carriers should be dried for 40 minutes at 30-37°C. Agency

guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then subculturing the slides after a 30-second holding time. Liquid expressed from the used towelette should also be subcultured. Tests are to be conducted in triplicate. Three product samples, representing three different batches, one of which is at least 60 days old, must be tested. Starting inocula must provide 75-125 x 10^6 CFU/mL on the parallel control surface. Additional organisms may be tested, using two batches of product. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. Subcultures of the liquid expressed from the used towelettes should be negative for growth. The study report must provide systematic and complete descriptions of the tests employed and the results obtained. Label directions must state that the towelette must be visibly wet (saturated) before use, and the treated surface must be visibly wet after use. Additionally, the label must identify the recommended maximum surface area to be treated, which must be reflective of the surface area tested in the study. The above Agency standards are presented in the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes. This guidance does not address products for use on utensils, glasses, food containers, dishes, and food processing equipment.

IV. Summary of Submitted Studies:

Note: All seven of the laboratory reports refer to the product as a "one-step" cleaner sanitizer. The product label does not use the "one-step" descriptor. The product directions require that the surfaces be pre-cleaned to remove visible soil. Efficacy testing was conducted using a 5% organic soil load, which was not necessary.

1. MRID 458633-01 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants – Rough Plastic – One Step Cleaner Sanitizer" for KIMTECH® Pre-Moistened Sanitizer Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – December 31, 2002. Laboratory Study Number 02-120915-106.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11229). Three lots (Lot Nos. 7345-90A, 7345-91A, and 7345-92A, the last being at least 60 days old at the time of testing) of the product, KIMTECH® Pre-Moistened Sanitizer Wipe, were tested using the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000, modified by EPA's April 12, 2001 Draft Interim Guidance on Towelette Sanitization. The product was received ready to use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sterile Nalgene® Polypropylene pans were used as carriers. The surface area of each pan was approximately 11" x 13.25" (145.75 in.^{2}; about 1 square foot). In total, 4 pans were tested for each product lot, representing a wiped surface area of four square feet. A deeply grooved pattern was mechanically pressed into the bottom of each pan to simulate a rough plastic surface. A 5.875" x 8" rough area (47 in.^{2}) on the bottom of each pan was inoculated with ~2.8 x 10^7 CFU/carrier of the test organism. The

inoculum was spread evenly over the pan in a drop-wise fashion, and allowed to air dry for 40 minutes at 37±2°C and a relative humidity of at least 50%. The pans were then wiped for 30 seconds at 23±1°C with a 12" x 12" wipe from the test lot, using one wipe per four pans. The wipe was folded into quarters, with one quarter used to wipe each pan. After 30 seconds contact time following the wiping, the remaining product was neutralized with AOAC Neutralizer Blanks with Sea Sand. Surviving bacteria were recovered using Tryptone Glucose Extract Agar with 25 mL/L AOAC Stock Neutralizer as the recovery medium. After incubation at 35±2°C for 47.25-48.25 hours, growth of the test organism was confirmed by macroscopic examination. In a similar manner, plate counts were conducted on the fluid expressed from the wipes immediately after wiping all four of the carriers. The percent reduction in numbers of test bacteria on the carriers and in the expressed fluid from the used wipes were calculated. Controls included sterility, viability, neutralizer effectiveness, and a numbers control.
Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

2. MRID 458633-02 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants – Rough Plastic – One Step Cleaner Sanitizer" for KIMTECH® Pre-Moistened Sanitizer Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – December 31, 2002. Laboratory Study Number 02-120916-106. This study was conducted against *Salmonella choleraesuis* (ATCC 10708). Two lots (Lot Nos. 7345-90A and 7345-91A) of the product, KIMTECH® Pre-Moistened Sanitizer Wipe, were tested using the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000, modified by EPA's April 12, 2001 Draft Interim Guidance on Towelette Sanitization. The product was received ready to use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sterile Nalgene® Polypropylene pans were used as carriers. The surface area of each pan was approximately 11" x 13.25" (145.75 in.^{2}; about 1 square foot). In total, 4 pans were tested for each product lot, representing a wiped surface area of four square feet. A deeply grooved pattern was mechanically pressed into the bottom of each pan to simulate a rough plastic surface. A 5.875" x 8" rough area (47 in.^{2}) on the bottom of each pan was inoculated with ~2.8 x 10^7 CFU/carrier of the test organism. The inoculum was spread evenly over the pan in a drop-wise fashion, and allowed to air dry for 40 minutes at 37±2°C and a relative humidity of at least 50%. The pans were then wiped for 30 seconds at 23±1°C with a 12" x 12" wipe from the test lot, using one wipe per four pans. The wipe was folded into quarters, with one quarter used to wipe each pan. After 30 seconds contact time following the wiping, the remaining product was neutralized with AOAC Neutralizer Blanks with Sea Sand. Surviving bacteria were recovered using Tryptone Glucose Extract Agar with 25 mL/L AOAC Stock Neutralizer as the recovery medium. After incubation at 35±2°C for 48 hours, growth of the test organism was confirmed by macroscopic examination. In a similar manner, plate counts were conducted on the fluid expressed from the wipes immediately after wiping all four of the carriers. The percent reduction in numbers of test bacteria on the carriers and in the expressed fluid from the used wipes were calculated. Controls included sterility, viability, neutralizer effectiveness, and a numbers control.
Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

3. MRID 458633-03 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants – Rough Plastic – One Step Cleaner Sanitizer" for KIMTECH® Pre-Moistened Sanitizer Wipe, by Kathleen A. Baxter. Study conducted at Hill Top

Research, Inc. Study completion date – December 16, 2002. Laboratory Study Number 02-120917-106.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 43895). Two lots (Lot Nos. 7345-90A and 7345-91A) of the product, KIMTECH® Pre-Moistened Sanitizer Wipe, were tested using the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000, modified by EPA's April 12, 2001 Draft Interim Guidance on Towelette Sanitization. The product was received ready to use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sterile Nalgene® Polypropylene pans were used as carriers. The surface area of each pan was approximately 11" x 13.25" (145.75 in.^{2}; about 1 square foot). In total, 4 pans were tested for each product lot, representing a wiped surface area of four square feet. A deeply grooved pattern was mechanically pressed into the bottom of each pan to simulate a rough plastic surface. A 5.875" x 8" rough area (47 in.^{2}) on the bottom of each pan was inoculated with ~2.8 x 10^7 CFU/carrier of the test organism. The inoculum was spread evenly over the pan in a drop-wise fashion, and allowed to air dry for 40 minutes at 37±2°C and a relative humidity of at least 50%. The pans were then wiped for 30 seconds at 23±1°C with a 12" x 12" wipe from the test lot, using one wipe per four pans. The wipe was folded into quarters, with one quarter used to wipe each pan. After 30 seconds contact time following the wiping, the remaining product was neutralized with AOAC Neutralizer Blanks with Sea Sand. Surviving bacteria were recovered using Tryptone Glucose Extract Agar with 25 mL/L AOAC Stock Neutralizer as the recovery medium. After incubation at 35±2°C for 48.25 hours, growth of the test organism was confirmed by macroscopic examination. In a similar manner, plate counts were conducted on the fluid expressed from the wipes immediately after wiping all four of the carriers. The percent reduction in numbers of test bacteria on the carriers and in the expressed fluid from the used wipes were calculated. Controls included sterility, viability, neutralizer effectiveness, and a numbers control.

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

4. MRID 458633-04 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants – Rough Plastic – One Step Cleaner Sanitizer" for KIMTECH® Pre-Moistened Sanitizer Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – December 31, 2002. Laboratory Study Number 02-120918-106.

This study was conducted against *Shigella boydii* (ATCC 9207). Two lots (Lot Nos. 7345-90A and 7345-91A) of the product, KIMTECH® Pre-Moistened Sanitizer Wipe, were tested using the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000, modified by EPA's April 12, 2001 Draft Interim Guidance on Towelette Sanitization. The product was received ready to use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sterile Nalgene® Polypropylene pans were used as carriers. The surface area of each pan was approximately 11" x 13.25" (145.75 in.^{2}; about 1 square foot). In total, 4 pans were tested for each product lot, representing a wiped surface area of four square feet. A deeply grooved pattern was mechanically pressed into the bottom of each pan to simulate a rough plastic surface. A 5.875" x 8" rough area (47 in.^{2}) on the bottom of each pan was inoculated with ~2.8 x 10^7 CFU/carrier of the test organism. The inoculum was spread evenly over the pan in a drop-wise fashion, and allowed to air dry for 40 minutes at 37±2°C and a relative humidity of at least 50%. The pans were then wiped for 30 seconds at 23±1°C with a 12" x 12" wipe from the test lot, using one wipe per four pans. The wipe was folded into quarters, with one quarter used

to wipe each pan. After 30 seconds contact time following the wiping, the remaining product was neutralized with AOAC Neutralizer Blanks with Sea Sand. Surviving bacteria were recovered using Tryptone Glucose Extract Agar with 25 mL/L AOAC Stock Neutralizer as the recovery medium. After incubation at 35±2°C for 47.5 hours, growth of the test organism was confirmed by macroscopic examination. In a similar manner, plate counts were conducted on the fluid expressed from the wipes immediately after wiping all four of the carriers. The percent reduction in numbers of test bacteria on the carriers and in the expressed fluid from the used wipes were calculated. Controls included sterility, viability, neutralizer effectiveness, and a numbers control.
Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

5. MRID 458633-05 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants – Rough Plastic – One Step Cleaner Sanitizer" KIMTECH® Pre-Moistened Sanitizer Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – December 16, 2002. Laboratory Study Number 02-120919-106.

This study was conducted against *Listeria monocytogenes* (ATCC 19115). Two lots (Lot Nos. 7345-90A and 7345-91A) of the product, KIMTECH® Pre-Moistened Sanitizer Wipe, were tested using the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000, modified by EPA's April 12, 2001 Draft Interim Guidance on Towelette Sanitization. The product was received ready to use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sterile Nalgene® Polypropylene pans were used as carriers. The surface area of each pan was approximately 11" x 13.25" (145.75 in.^{2}; about 1 square foot). In total, 4 pans were tested for each product lot, representing a wiped surface area of four square feet. A deeply grooved pattern was mechanically pressed into the bottom of each pan to simulate a rough plastic surface. A 5.875" x 8" rough area (47 in.^{2}) on the bottom of each pan was inoculated with ~2.8 x 10^7 CFU/carrier of the test organism. The inoculum was spread evenly over the pan in a drop-wise fashion, and allowed to air dry for 40 minutes at 37±2°C and a relative humidity of at least 50%. The pans were then wiped for 30 seconds at 21.5°C with a 12" x 12" wipe from the test lot, using one wipe per four pans. The wipe was folded into quarters, with one quarter used to wipe each pan. After 30 seconds contact time following the wiping, the remaining product was neutralized with AOAC Neutralizer Blanks with Sea Sand. Surviving bacteria were recovered using Brain Heart Infusion Agar with 25 mL/L AOAC Stock Neutralizer as the recovery medium. After incubation at 35±2°C for 48 hours, growth of the test organism was confirmed by macroscopic examination. In a similar manner, plate counts were conducted on the fluid expressed from the wipes immediately after wiping all four of the carriers. The percent reduction in numbers of test bacteria on the carriers and in the expressed fluid from the used wipes were calculated. Controls included sterility, viability, neutralizer effectiveness, and a numbers control.
Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

6. MRID 458633-06 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants – Rough Plastic – One Step Cleaner Sanitizer" for KIMTECH® Pre-Moistened Sanitizer Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – December 16, 2002. Laboratory Study Number 02-120920-106.

This study was conducted against *Listeria monocytogenes* (ATCC 15313). Two lots (Lot Nos. 7345-90A and 7345-91A) of the product, KIMTECH® Pre-Moistened Sanitizer Wipe, were tested using the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000, modified by EPA's April 12, 2001 Draft Interim Guidance on Towelette Sanitization. The product was received ready to use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sterile Nalgene® Polypropylene pans were used as carriers. The surface area of each pan was approximately 11" x 13.25" (145.75 in.^{2}; about 1 square foot). In total, 4 pans were tested for each product lot, representing a wiped surface area of four square feet. A deeply grooved pattern was mechanically pressed into the bottom of each pan to simulate a rough plastic surface. A 5.875" x 8" rough area (47 in.^{2}) on the bottom of each pan was inoculated with ~2.8 x 10^7 CFU/carrier of the test organism. The inoculum was spread evenly over the pan in a drop-wise fashion, and allowed to air dry for 40 minutes at 37±2°C and a relative humidity of at least 50%. The pans were then wiped for 30 seconds at 23±1°C with a 12" x 12" wipe from the test lot, using one wipe per four pans. The wipe was folded into quarters, with one quarter used to wipe each pan. After 30 seconds contact time following the wiping, the remaining product was neutralized with AOAC Neutralizer Blanks with Sea Sand. Surviving bacteria were recovered using Brain Heart Infusion Agar with 25 mL/L AOAC Stock Neutralizer as the recovery medium. After incubation at 35±2°C for 47 hours, growth of the test organism was confirmed by macroscopic examination. In a similar manner, plate counts were conducted on the fluid expressed from the wipes immediately after wiping all four of the carriers. The percent reduction in numbers of test bacteria on the carriers and in the expressed fluid from the used wipes were calculated. Controls included sterility, viability, neutralizer effectiveness, and a numbers control.

7. MRID 458633-07 "Modified AOAC Germicidal and Detergent Sanitizing Action of Disinfectants – Rough Plastic – One Step Cleaner Sanitizer" for KIMTECH® Pre-Moistened Sanitizer Wipe, by Kathleen A. Baxter. Study conducted at Hill Top Research, Inc. Study completion date – December 16, 2002. Laboratory Study Number 02-120921-106.

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Two lots (Lot Nos. 7345-90A and 7345-91A) of the product, KIMTECH® Pre-Moistened Sanitizer Wipe, were tested using the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000, modified by EPA's April 12, 2001 Draft Interim Guidance on Towelette Sanitization. The product was received ready to use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sterile Nalgene® Polypropylene pans were used as carriers. The surface area of each pan was approximately 11" x 13.25" (145.75 in.^{2}; about 1 square foot). In total, 4 pans were tested for each product lot, representing a wiped surface area of four square feet. A deeply grooved pattern was mechanically pressed into the bottom of each pan to simulate a rough plastic surface. A 5.875" x 8" rough area (47 in.^{2}) on the bottom of each pan was inoculated with ~2.8 x 10^7 CFU/carrier of the test organism. The inoculum was spread evenly over the pan in a drop-wise fashion, and allowed to air dry for 40 minutes at 37±2°C and a relative humidity of at least 50%. The pans were then wiped for 30 seconds at 23±1°C with a 12" x 12" wipe from the test lot, using one wipe per four pans. The wipe was folded into quarters, with one quarter used to wipe each pan. After 30 seconds contact time following the wiping, the remaining product was neutralized with AOAC Neutralizer Blanks with Sea Sand. Surviving bacteria were recovered using Tryptone Glucose Extract Agar with 25 mL/L AOAC Stock Neutralizer as the recovery medium. After incubation at 35±2°C for 46.5 hours, growth of the test organism was

confirmed by macroscopic examination. In a similar manner, plate counts were conducted on the fluid expressed from the wipes immediately after wiping all four of the carriers. The percent reduction in numbers of test bacteria on the carriers and in the expressed fluid from the used wipes were calculated. Controls included sterility, viability, neutralizer effectiveness, and a numbers control.

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

RESULTS

MRID Number	Organism	Lot Number	Numbers Control Count (CFU/4 sq. ft.)	Final Count, Carrier Surface (CFU/4 sq. ft.)	Reported % Reduction †
458633-01	*Staphylococcus aureus* *ATCC 6538*	7345-90A	8.3×10^7	$<1.1 \times 10^2$	>99.9999
		7345-91A	8.3×10^7	$<8.0 \times 10^1$	>99.9999
		7345-92A	9.2×10^7	$<2.0 \times 10^2$	>99.9998
	Escherichia coli *ATCC 11220*	7345-90A	1.1×10^8	$<1.2 \times 10^2$	>99.9999
		7345-91A	1.1×10^8	$<1.2 \times 10^2$	>99.9999
		7345-92A	9.6×10^7	$<1.0 \times 10^2$	>99.9999
458633-02	*Salmonella choleraesuis* *ATTC 10708*	7345-90A	1.1×10^8	$<1.0 \times 10^2$	>99.9999
		7345-91A	1.1×10^8	$<1.0 \times 10^2$	>99.9999
458633-03	*Escherichia coli* O157:H7 ATCC 43895	7345-90A	8.6×10^7	$<1.3 \times 10^2$	>99.9998
		7345-91A	8.6×10^7	$<1.4 \times 10^2$	>99.9998
458633-04	*Shigella boydii* *ATCC 9207*	7345-90A	1.7×10^8	$<2.2 \times 10^2$	>99.9999‡
		7345-91A	1.7×10^8	$<2.1 \times 10^2$	>99.9999‡
458633-05	*Listeria monocytogenes* ATCC 19115	7345-90A	1.0×10^8	$<1.6 \times 10^2$	>99.9998
		7345-91A	1.0×10^8	$<2.6 \times 10^2$	>99.9997
458633-06	*Listeria monocytogenes* ATCC 15313	7345-90A	1.8×10^8	$<1.3 \times 10^2$	>99.9999
		7345-91A	1.8×10^8	$<8.0 \times 10^1$	>99.9999
458633-07	*Klebsiella pneumoniae* *ATCC 15313*	7345-90A	1.1×10^8	$<1.1 \times 10^2$	>99.9999
		7345-91A	1.1×10^8	$<9.0 \times 10^1$	>99.9999

† All cultures of fluid expressed from used wipes were reported to result in $<1.0 \times 10^1$ CFU/mL.

V. Labeling:

1. The approved label, dated February 3, 2003, claims that the product can be used on grocery store carts. The Agency position at this time is grocery store carts, and any other food-contact equipment which cannot be immersed in a disinfectant product would be inadequately sanitized using a towelette product, which may not reach into all the nooks and crannies of the cart, as would immersion or similar application approach.

VI. Comments and Recommendations

1. The submitted efficacy data support the use of the product, KIMTECH® Pre-Moistened Sanitizer Wipe, as a sanitizer on hard, non-porous, rough plastic surfaces when exposed to the following organisms for a period of 30 seconds. The minimum exposure time allowed by the Agency for a sanitizer label claim against bacteria is 60 seconds.

Staphylococcus aureus (ATCC 6538)	(MRID No. 458633-01)
Escherichia coli	(MRID No. 458633-01)
Salmonella choleraesuis (10708)	(MRID No. 458633-02)
Escherichia coli O157:H7 (ATCC 43895)	(MRID No. 458633-03)
Shigella boydii (ATCC 9207)	(MRID No. 458633-04)
Listeria monocytogenes (ATCC 19115)	(MRID No. 458633-05)
Listeria monocytogenes (ATCC 15313)	(MRID No. 458633-06)
Klebsiella pneumoniae (ATCC 4352)	(MRID No. 458633-07)

EPA's April 12, 2001 draft interim guidance requires that all tests be conducted in triplicate. This is an error which will be corrected in succeeding documents. Only the original organisms required for a sanitizer must be tested in triplicate, and that was done. The duplicate tests conducted using additional organism for which label claims were made are acceptable. For the data submitted, at least a 5-log reduction in viability was observed when the product was tested on hard, non-porous, rough plastic surfaces for a contact time of 60 seconds in the presence of a 5% organic soil load (fetal bovine serum). Neutralization effectiveness testing showed positive growth of the organism in Tryptone Glucose Extract Agar (Brain Heart Infusion Agar for *Listeria monocytogenes*). No growth was evident in subcultures from liquid expressed from the test wipes. Other controls performed according to expectations. Greater than 4 ft^2 were tested per 12" x 12" wipe (1 ft^2 = 144 $in.^2$; 145.75 $in.^2$ were tested per set of four carriers).

2. The label claim for the use of this product on grocery carts must be removed.