# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
# WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

June 25, 2009

**MEMORANDUM**

Subject: Efficacy Review for EPA Company No. 4582-TE, Ultimate Clean
Barcode: 357853

From: Tajah L. Blackburn, Ph.D., Microbiologist 6/25/09
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Michele Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Emily Mitchell PM 34/ Stacey Grisby
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Colgate-Palmolive Company
New York, NY 10022

Formulations from Label

| Active Ingredient(s) | % by wt. |
|---|---|
| L-Lactic Acid | 2.00% |
| Other Ingredients | 98.00% |
| Total | 100.00% |

## I BACKGROUND

The product, Ultimate Clean, (EPA Reg. No. 4582-TE), is a new product for use as a dish detergent/sanitizer for limited to household/residential use. Ultimate Clean is identical in use and types of claims to Cleaning Magic II (EPA Reg. No. 3573-62). According to the registrant's letter (dated September 29, 2008), "pre-submission meetings between Colgate-Palmolive and AD staff to discuss registration requirements for Ultimate Clean were held on July 24, 2006, September 22, 2006, and March 19, 2007." Meeting notes detailed the following, as it relates to efficacy data;

July 24, 2006

A meeting was held on a proposed one-step dishwashing detergent/antibacterial product. Representatives of Colgate-Palmolive Company met with representatives of AD.

Efficacy

According to the meeting notes, "Mr. Harrison noted that the efficacy protocol provided by Colgate is a modification of the Germicidal Spray Product Test Method. It is the same protocol that was used by Procter and Gamble to register their dish detergent/antibacterial product, Cleaning Magic II (EPA Reg. No. 3573-62). Mr. Harrison also noted that the protocol was used to obtain an antibacterial claim (3 log kill) for the P&G product. The protocol appeared acceptable to AD staff, as long as the following modifications were made:

> Change the name *Salmonella choleraesuis* to *Salmonella enterica*
> Test 3 representative batches, one of which is at least 60 days old, against the test microorganisms.

Colgate also pointed out that the conditional registration approval for Cleaning Magic II required P&G to submit the efficacy protocol for AOAC Peer review. Colgate asked about the status of this review. Nancy Whyte indicated that she would check into this matter and apprise Colgate of the status."

Product Label

According to the registrant's meeting notes, "Mr. Harrison mentioned that the product label is limited to an antibacterial claim and that no sanitizer claims are made. According to Mr. Harrison, AD had previously determined, after consultation with the Science Advisory Panel, that a 3 log kill for a consumer or household product used for microbial control on dishes, dishware, utensils and cutlery was acceptable....Ms. Whyte stated that the 'term' germs could not be used on the label and that all claims referring to porous materials and plastic cutting boards should be removed. In addition, AD will probably object to the terms 'rids', 'biorenewable resources', and 'peace of mind'. Ms. Whyte also noted that no anti-viral claims will be permitted."

September 22, 2006

A second meeting was held on Colgate's proposed one-step antibacterial dishwashing product between Colgate and AD.

According to the meeting notes provided by Colgate, "Mr. Harrison opened the meeting by giving a brief overview of Colgate's dish detergent/antibacterial product and a summary of the issues that were discussed at the initial meeting. The main topic of discussion at the September 22 meeting was the inert ingredients and Colgate's understanding of the Agency's position."

March 19, 2007

According to the meeting notes provided by Colgate, "On March 19, 2007, a face to face meeting was held to obtain agreement on Colgate's proposed one-step antibacterial dishwashing product." The focus of the meeting was to address each inert ingredient in the dish detergent/sanitizer product and safety/dietary information.

The data package contained a letter from the registrant (September 29, 2008), meeting notes (Attachment I), two efficacy studies (MRID Nos. 475754-02 and -03), EPA Form 8570-1, EPA Form 8570-27, EPA Form 8570-34, Data Matrix (EPA Form 8570-35), Confidential Statement of Formula (EPA Form 8570-4), and the proposed label.

## II USE DIRECTIONS

The proposed product is a dish detergent/sanitizer for use on dishes, glasses, drain boards, sinks, microwaves, knives, storage areas, tongs, and lunch pails composed of chrome, glass, metal, vinyl, sealed wood, enamel, and fiberglass. Directions on the proposed label provided the following instructions for the use of the product:

Remove excess food from dishware, then dilute 1 part product to 20 parts water. Allow dishes to sit in solution for 30 seconds then wash and rinse thoroughly as you normally would.

## III AGENCY STANDARDS FOR PROPOSED CLAIMS

**No standards have been proposed for these claims.**

## IV SYNOPSIS OF SUBMITTED STUDIES

**1. MRID No. 475754-02, "Efficacy Testing of Antibacterial Dishwashing Detergent, Ultra density and Regular Density" Against *Staphylococcus aureus* (ATCC 6538) and *Salmonella enterica* (ATCC 10708) by Felicia Sellers. Study Completion Date—September 8, 2008. Laboratory Identification Numbers- MicroBioTest #443-104 and Charles River Dose Solution # AWR00013AX.**

This study was conducted against *Staphylococcus aureus* and *Salmonella enterica*. Three lots each of the products, Ultra Density (Lot Nos. UCB4FU2LP-13, UCB5FU2LP-13, and UCB6FU2LP-13) and Regular Density (Lot Nos. UCB4FR2LP-16, UCB5FR2LP-16, and UCB6FR2LP-16) were tested using AOAC Germicidal Spray Products Test, Official Methods of Analysis, 16th edition, 1995. Two of the lots for each product were the aged lots (Lots Nos. UCB6FU2LP-13 and UCB6FR2LP-16). Carriers were sterilized by placing them in evaporating dishes matted with filter paper, heating them in a hot air oven for two hours at 180°C. Each prepared culture was mixed 3-4 seconds, then allowed to settle for 10 minutes prior to use. An aliquot of each inoculum was transferred onto a 1 $in^2$ area on the sterile carriers and immediately spread uniformly over the entire area with a sterile glass rod. Each dish was promptly covered, and carriers were allowed to dry for 20-40 minutes at 37±2°C. Heat-inactivated horse serum was added to the inoculum to achieve a 5% concentration. Ten carriers for each organism/lot were treated with three (3) ml of the prepared test substance. The test substance was delivered at a 1:20 (v/v) dilution. The test material was spread on the carrier for a total of 30 seconds. Spreading was defined as: once the test substance was applied to a glass slide, a sterile glass rod was used to spread the material back and forth across the slide for approximately 15 seconds. The spreading continued in an up and down motion for the remainder of the 30 seconds. At the completion of spreading, the excess product run-off was collected; and then the carrier was transferred to a tube containing 20 ml DE. For the run-off sample, one ml was collected and transferred to a tube containing 10 ml DE. Tubes containing carriers were subjected to ultrasound for five minutes. Both the contents of the sonicated carrier tubes and the neutralized run-off samples were serially diluted in tenfold increments and duplicate one ml aliquots from selected dilutions were plated in duplicate TSA pour plates. Once solid, all plates were inverted and incubated for two days at 37±2°C in ambient air. Controls included those for numbers, neutralizer effectiveness, sterility, and organism confirmation. For the Test Acceptance Criteria, the carrier numbers controls should be at least $1.0 \times 10^6$ CFU/carrier but does not exceed $1.0 \times 10^7$ CFU/carrier. The excess product run-off numbers controls should be at least $1.0 \times 10^4$ CFU/ml but does not exceed $1.0 \times 10^7$ CFU/ml.

**2. MRID No. 475754-03 "Efficacy Testing of Antibacterial Dishwashing Detergent, Ultra density and Regular Density" Against *Escherichia coli* O157:H7 by Felicia Sellers. Study Completion Date—September 8, 2008. Laboratory Identification Numbers- MicroBioTest #443-105 and Charles River Dose Solution # AWR00014AX.**

This study was conducted against *Escherichia coli* O157:H7 (ATCC 43895). Two lots each of the products, Ultra Density (Lot Nos. UCB4FU2LP-13 and UCB5FU2LP-13) and Regular Density (Lot Nos. UCB4FR2LP-16 and UCB5FR2LP-16) were tested using AOAC Germicidal Spray Products Test, Official Methods of Analysis, 16th edition, 1995 (Protocol Number CP GLP 2007-007). Carriers were sterilized by placing them in evaporating dishes matted with filter paper, heating them in a hot air oven for two hours at 180°C. Each prepared culture was mixed 3-4 seconds, then allowed to settle for 10 minutes prior to use. An aliquot of each inoculum was transferred onto a 1 $in^2$ area on the sterile carriers and immediately spread uniformly over the entire area with a sterile glass rod. Each dish was promptly covered, and carriers were allowed to dry for 20-40 minutes at 37±2°C. Heat-inactivated horse serum was added to the inoculum to achieve a 5% concentration. Ten carriers for each organism/lot were treated with three (3) ml of the prepared test substance. The test substance was delivered at a 1:20 (v/v) dilution. The test material was spread on the carrier for a total of 30 seconds. Spreading was defined as: once the test substance was applied to a glass slide, a sterile glass rod was used to spread the material back and forth across the slide for approximately 15 seconds. The spreading continued in an up and down motion for the remainder of the 30 seconds. At the completion of spreading, the excess product run-off was collected; and then the carrier was transferred to a tube containing 20 ml DE. For the run-off sample, one ml was collected and transferred to a tube containing 10 ml DE. Tubes containing carriers were subjected to ultrasound for five minutes. Both the contents of the sonicated carrier tubes and the neutralized run-off samples were serially diluted in tenfold increments and duplicate one ml aliquots from selected dilutions were plated in duplicate TSA pour plates. Once solid, all plates were inverted and incubated for two days at 37±2°C in ambient air. Controls included those for numbers, neutralizer effectiveness, sterility, and organism confirmation. For the Test Acceptance Criteria, the carrier numbers controls should be at least $1.0 \times 10^6$ CFU/carrier but does not exceed $1.0 \times 10^7$ CFU/carrier. The excess product run-off numbers controls should be at least $1.0 \times 10^4$ CFU/ml but does not exceed $1.0 \times 10^7$ CFU/ml.

## V RESULTS

MRID No. 475754-02

Carrier Test Results--*Staphylococcus aureus* (Regular Density)

| Lot Number | Replicate | CFU recovered | $Log_{10}$ reduction |
|---|---|---|---|
| UCB4FR2LP-16 | 1 | < 1.0 x $10^1$ | >5.72 |
| | 2 | < 1.0 x $10^1$ | >5.72 |
| | 3 | < 1.0 x $10^1$ | >5.72 |
| | 4 | < 1.0 x $10^1$ | >5.72 |
| | 5 | < 1.0 x $10^1$ | >5.72 |
| | 6 | < 1.0 x $10^1$ | >5.72 |
| | 7 | 4.0 x $10^2$ | 4.12 |
| | 8 | < 1.0 x $10^1$ | >5.72 |
| | 9 | 1.0 x $10^1$ | 5.72 |
| | 10 | < 1.0 x $10^1$ | >5.72 |
| UCB5FR2LP-16 | 1 | 1.0 x $10^1$ | 5.72 |
| | 2 | < 1.0 x $10^1$ | >5.72 |
| | 3 | < 1.0 x $10^1$ | >5.72 |
| | 4 | < 1.0 x $10^1$ | >5.72 |
| | 5 | < 1.0 x $10^1$ | >5.72 |
| | 6 | 1.0 x $10^1$ | 5.72 |
| | 7 | < 1.0 x $10^1$ | >5.72 |
| | 8 | < 1.0 x $10^1$ | >5.72 |
| | 9 | 4.0 x $10^2$ | 4.12 |
| | 10 | < 1.0 x $10^1$ | >5.72 |
| UCB6FR2LP-16 (> 60 days old) | 1 | < 1.0 x $10^1$ | >5.72 |
| | 2 | < 1.0 x $10^1$ | >5.72 |
| | 3 | 1.0 x $10^2$ | 4.72 |
| | 4 | < 1.0 x $10^1$ | >5.72 |
| | 5 | 3.0 x 102 | 4.24 |
| | 6 | < 1.0 x $10^1$ | >5.72 |
| | 7 | < 1.0 x $10^1$ | >5.72 |
| | 8 | < 1.0 x $10^1$ | >5.72 |
| | 9 | < 1.0 x $10^1$ | >5.72 |
| | 10 | < 1.0 x $10^1$ | >5.72 |

Carrier Based Results for *Staphylococcus aureus* (Ultra Density)

| Lot Number | Replicate | CFU recovered | $Log_{10}$ reduction |
|---|---|---|---|
| UCB4FU2LP-13 | 1 | $3.0 \times 10^1$ | 5.24 |
| | 2 | $1.0 \times 10^1$ | 5.72 |
| | 3 | $1.2 \times 10^2$ | 4.64 |
| | 4 | $5.0 \times 10^1$ | 5.02 |
| | 5 | $2.0 \times 10^2$ | 4.42 |
| | 6 | $2.0 \times 10^1$ | 5.42 |
| | 7 | $5.0 \times 10^1$ | 5.02 |
| | 8 | $3.0 \times 10^1$ | 5.24 |
| | 9 | $2.0 \times 10^1$ | 5.42 |
| | 10 | $3.0 \times 10^1$ | 5.24 |
| UCB5FU2LP-13 | 1 | $<1.0 \times 10^1$ | >5.72 |
| | 2 | $3.0 \times 10^1$ | 5.24 |
| | 3 | $3.0 \times 10^1$ | 5.24 |
| | 4 | $3.0 \times 10^1$ | 5.24 |
| | 5 | $3.0 \times 10^1$ | 5.24 |
| | 6 | $<1.0 \times 10^1$ | >5.72 |
| | 7 | $1.0 \times 10^1$ | 5.72 |
| | 8 | $1.0 \times 10^1$ | 5.72 |
| | 9 | $1.0 \times 10^1$ | 5.72 |
| | 10 | $7.0 \times 10^1$ | 4.88 |
| UCB6FU2LP-13 (> 60 days old) | 1 | $2.0 \times 10^2$ | 4.42 |
| | 2 | $< 1.0 \times 10^1$ | >5.72 |
| | 3 | $1.0 \times 10^2$ | 4.72 |
| | 4 | $< 1.0 \times 10^1$ | >5.72 |
| | 5 | 3.0 x 102 | 4.24 |
| | 6 | $< 1.0 \times 10^1$ | >5.72 |
| | 7 | $< 1.0 \times 10^1$ | >5.72 |
| | 8 | $< 1.0 \times 10^1$ | >5.72 |
| | 9 | $< 1.0 \times 10^1$ | >5.72 |
| | 10 | $< 1.0 \times 10^1$ | >5.72 |

Runoff Test Results—*Staphylococcus aureus* (Regular Density)

| Lot Number | Replicate | CFU recovered | $Log_{10}$ reduction |
|---|---|---|---|
| UCB4FR2LP-16 | 1 | $6.5 \times 10^1$ | 4.23 |
| | 2 | $7.0 \times 10^1$ | 4.20 |
| | 3 | $6.0 \times 10^2$ | 4.26 |
| | 4 | $5.0 \times 10^0$ | 5.34 |
| | 5 | $6.0 \times 10^2$ | 4.26 |
| | 6 | $5.0 \times 10^0$ | 5.34 |
| | 7 | $6.0 \times 10^1$ | 4.26 |
| | 8 | $2.5 \times 10^1$ | 4.64 |
| | 9 | $6.5 \times 10^1$ | 4.23 |
| | 10 | $1.0 \times 10^1$ | 5.04 |
| UCB5FR2LP-16 | 1 | $1.0 \times 10^1$ | 5.04 |
| | 2 | $5.0 \times 10^0$ | 5.34 |
| | 3 | $<5.0 \times 10^0$ | >5.34 |
| | 4 | $2.0 \times 10^1$ | 4.74 |
| | 5 | $1.0 \times 10^1$ | 5.04 |
| | 6 | $1.5 \times 10^1$ | 4.87 |
| | 7 | $2.0 \times 10^1$ | 4.74 |
| | 8 | $2.5 \times 10^1$ | 4.64 |
| | 9 | $3.0 \times 10^1$ | 4.56 |
| | 10 | $1.0 \times 10^1$ | 5.04 |
| UCB6FR2LP-16 (> 60 days old) | 1 | $1.0 \times 10^1$ | 5.04 |
| | 2 | $1.0 \times 10^1$ | 5.04 |
| | 3 | $2.5 \times 10^1$ | 4.64 |
| | 4 | $5.0 \times 10^0$ | 5.34 |
| | 5 | $5.0 \times 10^0$ | 5.34 |
| | 6 | $5.0 \times 10^0$ | >5.34 |
| | 7 | $<5.0 \times 10^0$ | >5.34 |
| | 8 | $2.0 \times 10^1$ | 4.74 |
| | 9 | $< 5.0 \times 10^0$ | >5.34 |
| | 10 | $< 5.0 \times 10^0$ | >5.34 |

Runoff Test Results—*Staphylococcus aureus* (Ultra Density)

| Lot Number | Replicate | CFU recovered | $Log_{10}$ reduction |
|---|---|---|---|
| UCB4FU2LP-13 | 1 | $1.9 \times 10^2$ | 3.76 |
| | 2 | $2.2 \times 10^2$ | 3.70 |
| | 3 | $3.7 \times 10^2$ | 3.47 |
| | 4 | $3.1 \times 10^2$ | 3.55 |
| | 5 | $4.0 \times 10^2$ | 3.44 |
| | 6 | $3.1 \times 10^2$ | 3.44 |
| | 7 | $1.6 \times 10^2$ | 3.55 |
| | 8 | $3.7 \times 10^2$ | 3.84 |
| | 9 | $2.0 \times 10^2$ | 3.74 |
| | 10 | $2.5 \times 10^2$ | 3.64 |
| UCB5FU2LP-13 | 1 | $2.4 \times 10^2$ | 3.66 |
| | 2 | $1.3 \times 10^2$ | 3.93 |
| | 3 | $3.8 \times 10^2$ | 3.46 |
| | 4 | $2.3 \times 10^2$ | 3.68 |
| | 5 | $2.3 \times 10^2$ | 3.68 |
| | 6 | $3.8 \times 10^2$ | 3.46 |
| | 7 | $2.4 \times 10^2$ | 3.66 |
| | 8 | $2.2 \times 10^2$ | 3.70 |
| | 9 | $9.5 \times 10^1$ | 4.06 |
| | 10 | $2.9 \times 10^2$ | 3.58 |
| UCB6FU2LP-13 (> 60 days old) | 1 | $3.8 \times 10^2$ | 3.46 |
| | 2 | $4.2 \times 10^2$ | 3.42 |
| | 3 | $6.8 \times 10^2$ | 3.21 |
| | 4 | $5.6 \times 10^2$ | 3.29 |
| | 5 | $3.1 \times 10^2$ | 3.55 |
| | 6 | $6.4 \times 10^2$ | 3.24 |
| | 7 | $2.2 \times 10^2$ | 3.70 |
| | 8 | $4.2 \times 10^2$ | 3.42 |
| | 9 | $3.8 \times 10^2$ | 3.46 |
| | 10 | $3.7 \times 10^2$ | 3.47 |

Carrier Test Results—*Salmonella enterica* (Regular Density)

| Lot Number | Replicate | CFU recovered | $Log_{10}$ reduction |
|---|---|---|---|
| UCB4FR2LP-16 | 1 | $< 1.0 \times 10^1$ | >5.05 |
| | 2 | $< 1.0 \times 10^1$ | >5.05 |
| | 3 | $2.0 \times 10^2$ | 3.75 |
| | 4 | $< 1.0 \times 10^1$ | >5.05 |
| | 5 | $1.0 \times 10^2$ | 4.05 |
| | 6 | $< 1.0 \times 10^1$ | >5.05 |
| | 7 | $1.0 \times 10^2$ | 4.05 |
| | 8 | $3.0 \times 10^2$ | 3.58 |
| | 9 | $4.0 \times 10^2$ | 3.45 |
| | 10 | $2.0 \times 10^1$ | 4.75 |
| UCB5FR2LP-16 | 1 | $<1.0 \times 10^1$ | >5.05 |
| | 2 | $< 1.0 \times 10^1$ | >5.05 |
| | 3 | $3.0 \times 10^2$ | 3.58 |
| | 4 | $< 1.0 \times 10^1$ | >5.05 |
| | 5 | $< 1.0 \times 10^1$ | >5.05 |
| | 6 | $1.0 \times 10^1$ | 5.05 |
| | 7 | $< 1.0 \times 10^1$ | >5.05 |
| | 8 | $< 1.0 \times 10^1$ | >5.05 |
| | 9 | $<1.0 \times 10^1$ | >5.05 |
| | 10 | $1.0 \times 10^2$ | 4.05 |
| UCB6FR2LP-16 (> 60 days old) | 1 | $1.0 \times 10^2$ | 4.05 |
| | 2 | $< 1.0 \times 10^1$ | >5.05 |
| | 3 | $<1.0 \times 10^2$ | >5.05 |
| | 4 | $3.0 \times 10^2$ | 3.58 |
| | 5 | $< 1.0 \times 10^1$ | >5.05 |
| | 6 | $3.0 \times 10^2$ | 3.58 |
| | 7 | $< 1.0 \times 10^1$ | >5.05 |
| | 8 | $< 1.0 \times 10^1$ | >5.05 |
| | 9 | $< 1.0 \times 10^1$ | >5.05 |
| | 10 | $1.0 \times 10^2$ | 4.05 |

Carrier Test Results—*Salmonella enterica* (Ultra Density)

| Lot Number | Replicate | CFU recovered | $Log_{10}$ reduction |
|---|---|---|---|
| UCB4FU2LP-13 | 1 | $< 1.0 \times 10^1$ | >5.05 |
| | 2 | $< 1.0 \times 10^1$ | >5.05 |
| | 3 | $< 1.0 \times 10^1$ | >5.05 |
| | 4 | $< 1.0 \times 10^1$ | >5.05 |
| | 5 | $< 1.0 \times 10^1$ | >5.05 |
| | 6 | $1.0 \times 10^2$ | 4.05 |
| | 7 | $2.0 \times 10^2$ | 3.75 |
| | 8 | $< 1.0 \times 10^1$ | >5.05 |
| | 9 | $< 1.0 \times 10^1$ | >5.05 |
| | 10 | $1.0 \times 10^2$ | 4.05 |
| UCB5FU2LP-13 | 1 | $<1.0 \times 10^1$ | >5.05 |
| | 2 | $3.0 \times 10^1$ | 4.58 |
| | 3 | $<1.0 \times 10^1$ | >5.05 |
| | 4 | $< 1.0 \times 10^1$ | >5.05 |
| | 5 | $< 1.0 \times 10^1$ | >5.05 |
| | 6 | $<1.0 \times 10^1$ | >5.05 |
| | 7 | $< 1.0 \times 10^1$ | >5.05 |
| | 8 | $< 1.0 \times 10^1$ | >5.05 |
| | 9 | $<1.0 \times 10^1$ | >5.05 |
| | 10 | $<1.0 \times 10^1$ | >5.05 |
| UCB6FU2LP-13 (> 60 days old) | 1 | $1.0 \times 10^2$ | 4.05 |
| | 2 | $< 1.0 \times 10^1$ | >5.05 |
| | 3 | $2.0 \times 10^2$ | 3.75 |
| | 4 | $< 1.0 \times 10^1$ | >5.05 |
| | 5 | $< 1.0 \times 10^1$ | >5.05 |
| | 6 | $< 1.0 \times 10^1$ | >5.05 |
| | 7 | $< 1.0 \times 10^1$ | >5.05 |
| | 8 | $< 1.0 \times 10^1$ | >5.05 |
| | 9 | $< 1.0 \times 10^1$ | >5.05 |
| | 10 | $< 1.0 \times 10^1$ | >5.05 |

Runoff Test Results—*Salmonella enterica* (Regular Density)

| Lot Number | Replicate | CFU recovered | $Log_{10}$ reduction |
|---|---|---|---|
| UCB4FR2LP-16 | 1 | $1.0 \times 10^1$ | 4.43 |
| | 2 | $< 5.0 \times 10^0$ | >4.73 |
| | 3 | $< 5.0 \times 10^0$ | >4.73 |
| | 4 | $< 5.0 \times 10^0$ | >4.73 |
| | 5 | $< 5.0 \times 10^0$ | >4.73 |
| | 6 | $1.5 \times 10^1$ | 4.26 |
| | 7 | $< 5.0 \times 10^0$ | >4.73 |
| | 8 | $5.0 \times 10^0$ | 4.73 |
| | 9 | $< 5.0 \times 10^0$ | >4.73 |
| | 10 | $5.0 \times 10^0$ | 4.73 |
| UCB5FR2LP-16 | 1 | $< 5.0 \times 10^0$ | >4.73 |
| | 2 | $1.0 \times 10^1$ | 4.43 |
| | 3 | $5.0 \times 10^0$ | 4.73 |
| | 4 | $< 5.0 \times 10^0$ | >4.73 |
| | 5 | $< 5.0 \times 10^0$ | >4.73 |
| | 6 | $< 5.0 \times 10^0$ | >4.73 |
| | 7 | $5.0 \times 10^0$ | 4.73 |
| | 8 | $< 5.0 \times 10^0$ | >4.73 |
| | 9 | $< 5.0 \times 10^0$ | >4.73 |
| | 10 | $5.0 \times 10^0$ | 4.73 |
| UCB6FR2LP-16 (> 60 days old) | 1 | $< 5.0 \times 10^0$ | >4.73 |
| | 2 | $< 5.0 \times 10^0$ | >4.73 |
| | 3 | $4.0 \times 10^1$ | 3.83 |
| | 4 | $< 5.0 \times 10^0$ | >4.73 |
| | 5 | $< 5.0 \times 10^0$ | >4.73 |
| | 6 | $5.0 \times 10^0$ | 4.73 |
| | 7 | $< 5.0 \times 10^0$ | >4.73 |
| | 8 | $< 5.0 \times 10^0$ | >4.73 |
| | 9 | $5.0 \times 10^0$ | 4.73 |
| | 10 | $< 5.0 \times 10^0$ | >4.73 |

Carrier Test Results—*Escherichia coli* O157:H7 (Regular Density)

| Lot Number | Replicate | CFU recovered | $Log_{10}$ reduction |
|---|---|---|---|
| UCB4FR2LP-16 | 1 | $1.0 \times 10^1$ | 5.43 |
| | 2 | $< 1.0 \times 10^1$ | >5.43 |
| | 3 | $< 1.0 \times 10^1$ | >5.43 |
| | 4 | $< 1.0 \times 10^1$ | >5.43 |
| | 5 | $< 1.0 \times 10^1$ | >5.43 |
| | 6 | $< 1.0 \times 10^1$ | >5.43 |
| | 7 | $1.0 \times 10^1$ | 5.43 |
| | 8 | $< 1.0 \times 10^1$ | >5.43 |
| | 9 | $< 1.0 \times 10^1$ | >5.43 |
| | 10 | $1.0 \times 10^1$ | 5.43 |
| UCB5FR2LP-16 | 1 | $<1.0 \times 10^1$ | >5.43 |
| | 2 | $3.0 \times 10^1$ | 4.95 |
| | 3 | $<1.0 \times 10^1$ | >5.43 |
| | 4 | $< 1.0 \times 10^1$ | >5.43 |
| | 5 | $< 1.0 \times 10^1$ | >5.43 |
| | 6 | $<1.0 \times 10^1$ | >5.43 |
| | 7 | $1.0 \times 10^1$ | 5.43 |
| | 8 | $< 1.0 \times 10^1$ | >5.43 |
| | 9 | $<1.0 \times 10^1$ | >5.43 |
| | 10 | $<1.0 \times 10^1$ | >5.43 |

Carrier Test Results—*Escherichia coli* O157:H7 (Ultra Density)

| Lot Number | Replicate | CFU recovered | $Log_{10}$ reduction |
|---|---|---|---|
| UCB4FU2LP-13 | 1 | $1.0 \times 10^1$ | 5.43 |
| | 2 | $1.0 \times 10^1$ | 5.43 |
| | 3 | $< 1.0 \times 10^1$ | >5.43 |
| | 4 | $7.0 \times 10^1$ | >4.59 |
| | 5 | $< 1.0 \times 10^1$ | >5.43 |
| | 6 | $1.0 \times 10^1$ | 5.43 |
| | 7 | $1.0 \times 10^1$ | 5.43 |
| | 8 | $4.0 \times 10^1$ | 4.83 |
| | 9 | $5.0 \times 10^1$ | 4.73 |
| | 10 | $<1.0 \times 10^1$ | >5.43 |
| UCB5FU2LP-13 | 1 | $<1.0 \times 10^1$ | >5.43 |
| | 2 | $<1.0 \times 10^1$ | >5.43 |
| | 3 | $2.0 \times 10^1$ | 5.13 |
| | 4 | $< 1.0 \times 10^1$ | >5.43 |
| | 5 | $2.0 \times 10^1$ | 5.13 |
| | 6 | $<1.0 \times 10^1$ | >5.43 |
| | 7 | $<1.0 \times 10^1$ | >5.43 |
| | 8 | $< 1.0 \times 10^1$ | >5.43 |
| | 9 | $2.0 \times 10^1$ | 5.13 |
| | 10 | $<1.0 \times 10^1$ | >5.43 |

Runoff Test Results—*Salmonella enterica* (Ultra Density)

| Lot Number | Replicate | CFU recovered | $Log_{10}$ reduction |
|---|---|---|---|
| UCB4FU2LP-13 | 1 | $< 5.0 \times 10^0$ | >4.73 |
| | 2 | $5.0 \times 10^0$ | >4.73 |
| | 3 | $< 5.0 \times 10^0$ | >4.73 |
| | 4 | $< 5.0 \times 10^0$ | >4.73 |
| | 5 | $< 5.0 \times 10^0$ | >4.73 |
| | 6 | $< 5.0 \times 10^0$ | >4.73 |
| | 7 | $< 5.0 \times 10^0$ | >4.73 |
| | 8 | $< 5.0 \times 10^0$ | >4.73 |
| | 9 | $< 5.0 \times 10^0$ | >4.73 |
| | 10 | $< 5.0 \times 10^0$ | >4.73 |
| UCB5FU2LP-13 | 1 | $1.0 \times 10^1$ | 4.43 |
| | 2 | $< 5.0 \times 10^0$ | >4.73 |
| | 3 | $< 5.0 \times 10^0$ | >4.73 |
| | 4 | $1.0 \times 10^1$ | 4.43 |
| | 5 | $< 5.0 \times 10^0$ | >4.73 |
| | 6 | $5.0 \times 10^0$ | 4.73 |
| | 7 | $<5.0 \times 10^0$ | >4.73 |
| | 8 | $< 5.0 \times 10^0$ | >4.73 |
| | 9 | $< 5.0 \times 10^0$ | >4.73 |
| | 10 | $5.0 \times 10^0$ | 4.73 |
| UCB6FU2LP-13 (> 60 days old) | 1 | $< 5.0 \times 10^0$ | >4.73 |
| | 2 | $< 5.0 \times 10^0$ | >4.73 |
| | 3 | $< 5.0 \times 10^0$ | >4.73 |
| | 4 | $2.0 \times 10^1$ | 4.13 |
| | 5 | $< 5.0 \times 10^0$ | >4.73 |
| | 6 | $<5.0 \times 10^0$ | >4.73 |
| | 7 | $5.0 \times 10^0$ | 4.73 |
| | 8 | $< 5.0 \times 10^0$ | >4.73 |
| | 9 | $1.0 \times 10^1$ | 4.43 |
| | 10 | $< 5.0 \times 10^0$ | >4.73 |

The carrier numbers controls were at least $1.0 \times 10^6$ CFU/carrier and did not exceed $1.0 \times 10^7$ CFU/carrier. The excess product run-off numbers controls were at least $1.0 \times 10^4$ CFU/ml and did not exceed $1.0 \times 10^7$ CFU/ml.

Runoff Test Results—*Escherichia coli* O157:H7 (Regular Density)

| Lot Number | Replicate | CFU recovered | $Log_{10}$ reduction |
|---|---|---|---|
| UCB4FR2LP-16 | 1 | $< 5.0 \times 10^0$ | >5.55 |
| | 2 | $<5.0 \times 10^0$ | >5.55 |
| | 3 | $< 5.0 \times 10^0$ | >5.55 |
| | 4 | $< 5.0 \times 10^0$ | >5.55 |
| | 5 | $< 5.0 \times 10^0$ | >5.55 |
| | 6 | $< 5.0 \times 10^0$ | >5.55 |
| | 7 | $< 5.0 \times 10^0$ | >5.55 |
| | 8 | $< 5.0 \times 10^0$ | >5.55 |
| | 9 | $< 5.0 \times 10^0$ | >5.55 |
| | 10 | $< 5.0 \times 10^0$ | >5.55 |
| UCB5FR2LP-16 | 1 | $< 5.0 \times 10^0$ | >5.55 |
| | 2 | $< 5.0 \times 10^0$ | >5.55 |
| | 3 | $< 5.0 \times 10^0$ | >5.55 |
| | 4 | $< 5.0 \times 10^0$ | >5.55 |
| | 5 | $< 5.0 \times 10^0$ | >5.55 |
| | 6 | $< 5.0 \times 10^0$ | >5.55 |
| | 7 | $1.0 \times 10^1$ | 5.25 |
| | 8 | $< 5.0 \times 10^0$ | >5.55 |
| | 9 | $< 5.0 \times 10^0$ | >5.55 |
| | 10 | $<5.0 \times 10^0$ | >5.55 |

Runoff Test Results—*Escherichia coli* O157:H7 (Ultra Density)

| Lot Number | Replicate | CFU recovered | $Log_{10}$ reduction |
|---|---|---|---|
| UCB4FU2LP-13 | 1 | $5.0 \times 10^0$ | >5.55 |
| | 2 | $<5.0 \times 10^0$ | >5.55 |
| | 3 | $< 5.0 \times 10^0$ | >5.55 |
| | 4 | $< 5.0 \times 10^0$ | >5.55 |
| | 5 | $< 5.0 \times 10^0$ | >5.55 |
| | 6 | $< 5.0 \times 10^0$ | >5.55 |
| | 7 | $< 5.0 \times 10^0$ | >5.55 |
| | 8 | $< 5.0 \times 10^0$ | >5.55 |
| | 9 | $< 5.0 \times 10^0$ | >5.55 |
| | 10 | $< 5.0 \times 10^0$ | >5.55 |
| UCB5FU2LP-13 | 1 | $< 5.0 \times 10^0$ | >5.55 |
| | 2 | $< 5.0 \times 10^0$ | >5.55 |
| | 3 | $< 5.0 \times 10^0$ | >5.55 |
| | 4 | $< 5.0 \times 10^0$ | >5.55 |
| | 5 | $< 5.0 \times 10^0$ | >5.55 |
| | 6 | $5.0 \times 10^0$ | 5.55 |
| | 7 | $2.5 \times 10^1$ | 4.86 |
| | 8 | $< 5.0 \times 10^0$ | >5.55 |
| | 9 | $< 5.0 \times 10^0$ | >5.55 |
| | 10 | $2.0 \times 10^1$ | 4.95 |

The carrier numbers controls were at least $1.0 \times 10^6$ CFU/carrier and did not exceed $1.0 \times 10^7$ CFU/carrier. The excess product run-off numbers controls were at least $1.0 \times 10^4$ CFU/ml and did not exceed $1.0 \times 10^7$ CFU/ml.

## VI CONCLUSIONS

1. The submitted efficacy data (MRID 475754-02) support the use of the product, Ultimate Clean (Regular Density), as a one-step dishwashing detergent/antibacterial product against *E. coli* O157:H7, *Staphylococcus aureus*, and *Salmonella enterica* for a contact time of 30 seconds when prepared at a 1:20 use dilution in the presence of 5% organic soil load. At least a 3-log reduction was demonstrated.

2. The submitted efficacy data (MRID 475754-03) support the use of the product, Ultimate Clean (Ultra Density), as a one-step dishwashing detergent/antibacterial product against *E. coli* O157:H7, *Staphylococcus aureus*, and *Salmonella enterica* for a contact time of 30 seconds when prepared at a 1:20 use dilution in the presence of 5% organic soil load. At least a 3-log reduction was demonstrated.

## VII RECOMMENDATIONS

1. The proposed label claims are acceptable regarding the use of the product, Ultimate Clean, as a one-step dishwashing detergent/antibacterial product against *Staphylococcus aureus* (ATCC 6538), *Salmonella enterica* (ATCC 10708), and *Escherichia coli* O157:H7 (ATCC 43895) for a 30 second contact time in the presence of 5% organic soil. *Escherichia coli* and *Escherichia coli* O157:H7 cannot be used interchangeably. The registrant should clarify which product is the Ultra Density versus the Regular Density; and is the proposed label for both products?

2. During the pre-registration discussions, it was determined that application of the product was limited to immersion of dishware, dishes, utensils and cutlery. Based on the referenced discussion, several of the use sites must be removed from the label (e.g., sink faucets, sink fixtures/handles, stove tops, oven handles/knobs, countertops, appliances, microwaves, cabinets, can openers, cupboards, kitchen tables, dining room tables, breakfast tables, grills, handrails, metal blinds, inside of dishwashers, inside freezer, inside refrigerator, kitchen surfaces, litter boxes, ovens, garbage cans/bins, refrigerator, snack counter, bar counter, breakfast counter, storage areas, under sinks, washable walls, washing machines, kitchen windows/window sills, light switches, chairs, etc.). Additionally, Nancy Whyte requested removal of plastic cutting boards from the proposed label, as cited in the pre-registration notes.

3. During the pre-meeting discussions, it was determined that the product label is limited to an "antibacterial claim", and that no sanitizer claims are made. As the Agency's accepted test method to support sanitization claims was not conducted, claims for sanitization must be removed from the proposed label.

4. The following claims must be removed from the proposed label:

--Pure
--Safe
--Mild
--Gentle
--A clean that is good for my kids and great grandkids

--Healthy
--Rapidly, quickly, rapid-action
--naturally-derived, plant-based, plant-derived
--safely
--New formula contains lactic acid ingredient that is commonly found in foods like yogurt, like cheese, wine
--biorenewable resources
--peace of mind
--mother nature
--nature
--renewable resources
--natural preservative
--a natural byproduct that preserves
--Gives me 360 degree protection
--tailor-made protection
--soft