

US EPA ARCHIVE DOCUMENT



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

May 3, 2001

**MEMORANDUM:**

**Subject:** Product Efficacy Review for EPA Reg. No.: 777-68 / Lysol Touch-Ups  
DP Barcode: D274047  
Case No: 008454

**From:** Ian Blackwell, Biologist  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510C)

*Ian Blackwell*

**Through:** Emily Mitchell, Team Leader  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510C)

*Emily Mitchell 7/11/01*

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

**To:** Velma Noble, PM 31 / Jackie Campbell  
Regulatory Management Branch  
Antimicrobials Division (7510C)

**Applicant:** Reckitt Benckiser, Inc.

**FORMULATION FROM LABEL:**

Active Ingredient(s):  
Alkyl Dimethyl Benzyl Ammonium Chlorides  
Other Ingredient(s):  
Total:

% by wt.  
0.28  
99.72  
100.00%

**BACKGROUND:** Reckitt Benckiser has seven product efficacy studies to support alternate formulations and additional efficacy claims of their product "Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Wipes." As this product has already been registered, some of these studies are considered confirmatory data. The MRID Numbers are 453676-01 through 453676-07. The studies were conducted by Reckitt Benckiser, Microbiology Laboratory and ViroMed Biosafety Laboratories.

**RECOMMENDATIONS:** PSB findings are:

1. MRID Number 453676-01: "Disinfectant Efficacy Testing in The Presence of Organic Soil," by Kyle T. Smith. Reckitt Benckiser, Microbiology Laboratory. Study ID Number M.S.#2000-077. Study Completion Date 8/22/2000.

This confirmatory study was conducted to determine the efficacy of "Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Wipes" as disinfectants. This product was tested against *Staphylococcus aureus* (ATCC 6538), *Salmonella choleraesuis* (ATCC 10708) and *Pseudomonas aeruginosa* (ATCC 15442). The study was conducted using a modification of the AOAC Germicidal Spray Test Method. The test substance was applied as packaged, with no dilution, for a ten minute exposure at 19-22.5 °C. Under the conditions of this study, "Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Wipes" were demonstrated to be effective disinfectants.

2. MRID Number 453676-02: "Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection" by Mary J. Miller. ViroMed Biosafety Laboratories. Study ID Number 10062. Study Completion Date 1/19/2001.

This study was conducted to determine the virucidal efficacy of "Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Wipes" against human Respiratory syncytial virus (ATCC VR-26, Strain Long). The study was conducted using the towelettes as supplied (undiluted) with a 30-second exposure at 22°C in the presence of 10% Fetal Bovine Serum as a soil load. Under the conditions of this study, "Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Wipes" was demonstrated to be an effective virucide against human Respiratory syncytial virus (ATCC VR-26, Strain Long) when applied undiluted at 22°C for 30 seconds in the presence of 10% Fetal Bovine Serum.

3. MRID Number 453676-03: "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Pre-Saturated Towelette Product Application)" by Jolene R. Kinston. ViroMed Biosafety Laboratories. Study ID Number 9531. Study Completion Date 2/15/2001.

This study was conducted to evaluate the efficacy of "Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Wipes" as sanitizers for inanimate, non-food contact surfaces. A solution containing *Streptococcus pyogenes* (ATCC #19615) and 5% Fetal Bovine Serum was used to contaminate the test slides. The assay was conducted by wiping contaminated slides with the product wipes/towelettes for five seconds at 21°C. Under the conditions of this study, "Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Wipes" were demonstrated to be effective sanitizers against hard, non-porous surfaces contaminated with *Streptococcus pyogenes* (ATCC #19615).

4. MRID Number 453676-04: "Standard test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Presaturated Towelette Product Application)" by Jolene R. Kingston. ViroMed Biosafety Laboratories. Study ID number 9532. Study Completion Date 2/12/2001.

This study was conducted to ability of "Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Wipes" to sanitize hard, non-porous surfaces contaminated with *Campylobacter jejuni* (ATCC #29428). The assay was conducted by wiping contaminated glass and porcelain slides with the product wipes/towelettes for five seconds at 22-23°C. Under the conditions of this study, "Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Wipes" were demonstrated to be effective sanitizers against *Campylobacter jejuni* (ATCC #29428) on **glass, but not on porcelain tile surfaces.**

5. MRID Number 453676-05: "Disinfectant Efficacy Testing in The Presence of Organic Soil" by Kyle T. Smith. Reckitt Benckiser, Inc. Study ID Number M.S. #2000-0096. Study Completion Date 11/21/2000.

This study was conducted to determine the ability of "Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Wipes" to sanitizer hard, non-porous surfaces contaminated with *Escherichia coli* 0157:H7 (ATCC #43888). The assay was conducted by wiping contaminated glass and porcelain slides with the product wipes/towelettes for five seconds at 22-23°C. The liquid expressed from the wipes was left in contact with the carrier for 30 seconds. Under the conditions of this study, "Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Wipes" were demonstrated to be effective sanitizers against *Escherichia coli* 0157:H7 (ATCC #43888) on **glass, but not on porcelain tile surfaces.**

6. MRID Number 453676-06: "Disinfectant Efficacy Testing in The Presence of Organic Soil" by Kyle T. Smith. Reckitt Benckiser, Microbiology Laboratory. Study ID Number M.S. # 2000-0097. Study completion date 11/21/2000.

This test was conducted to determine the ability of the test product to sanitize a hard, non-porous surface contaminated with *Salmonella choleraesuis* (ATCC #10708). This study used a modification of the ASTM Standard Test Method for

Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces. The conditions of the study were to test glass or tile carriers contaminated with *Salmonella choleraesuis* (ATCC #10708) by wiping the carrier with the test wipe and leaving it exposed to the (undiluted) liquid antimicrobial from the wipe for 30 seconds, at 20.1-20.9°C in the presence of horse serum as a soil load. Under the conditions of this study, the test product was demonstrated to provide effective sanitization against *Salmonella choleraesuis* (ATCC 10708) on **glass, but not on porcelain tile surfaces.**

7. MRID Number 453676-07: "Disinfectant Efficacy Testing in The Presence of Organic Soil" by Kyle T. Smith. Reckitt Benckiser, Microbiology Laboratory. Study ID Number M.S. # 2000-0120. Study completion date 11/21/2000.

This study was conducted to determine the ability of the test product to sanitize surfaces contaminated with *Listeria monocytogenes* (ATCC #7644). This study used a modification of the ASTM Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces. The conditions of the study were to test a glass or tile carrier contaminated with *Listeria monocytogenes* (ATCC #7644) by wiping the carrier with the test wipe and leaving it exposed to the (undiluted) liquid antimicrobial from the wipe for 30 seconds, at 22.0-25.7 °C in the presence of horse serum as a soil load. Under the conditions of this study, the test product was demonstrated to be an effective sanitizer against hard, non-porous surfaces (i.e., porcelain tiles and glass slides) contaminated with *Listeria monocytogenes* (ATCC #7644).

#### **LABELING:**

1. The submitted label contains statements that this product is an effective sanitizer against *Campylobacter jejuni* (ATCC 29428). The submitted data (MRID Number 453676-04) did **not** demonstrate that this product was effective in sanitizing porcelain surfaces contaminated with this bacterial species within ten seconds. Label statements claiming or implying that this product is an effective sanitizer against *Campylobacter jejuni* on porcelain tile within ten seconds are not supported and must be removed from the product label. The label should specify that this product is an effective sanitizer of *Campylobacter jejuni* (ATCC 29428) on glass.
2. The submitted label contains statements that this product is an effective sanitizer against *Escherichia coli* (ATCC 43888). The submitted data (MRID Number 453676-04) did **not** demonstrate that this product was effective in sanitizing porcelain tile surfaces contaminated with this bacterial species in the allotted ten second period. Label statements claiming or implying that this product is an effective sanitizer against *Escherichia coli* on porcelain tile within ten seconds are

not supported and must be removed from the product label. The label should state that this product is an effective sanitizer of glass surfaces contaminated with *Escherichia coli* (ATCC 43888).

3. The submitted label contains statements that this product is an effective sanitizer against *Salmonella choleraesuis* (ATCC 10708). The submitted data (MRID Number 453676-04) did **not** demonstrate that this product was effective in sanitizing porcelain tile surfaces contaminated with this bacterial species in ten seconds. Label statements claiming or implying that this product is an effective sanitizer against porcelain tile surfaces contaminated with *Salmonella choleraesuis* within ten seconds are not supported and must be removed from the product label. The label should state that this product is an effective sanitizer of glass surfaces contaminated with *Salmonella choleraesuis* (ATCC 10708).
4. The submitted label contains claims of efficacy against fungi and molds. The registrant has not submitted any data to support such claim with this submission, nor has there been approval for fungi or molds in the past. All such claims must be removed from the product label.
5. If the product label is to state that "Lysol Brand Pre-Moistened Bathroom Touch-Ups Disinfecting Wipes" are effective sanitizers of surfaces in 30 seconds, the label must clarify the following:
  - a. That these surfaces must be hard, non-porous surfaces.
  - b. That this sanitization or reduction of 99.9% of bacteria in ten seconds does not include *Salmonella choleraesuis*, *Escherichia coli* or *Campylobacter jejuni*.