

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

December 2, 2002

MEMORANDUM:

Subject: Efficacy Review EPA Reg.No.777-68
Lysol Brand Pre-Moistened Touch-Ups
DP Barcode 285970
Case No. 008454

From: Nancy Whyte, Microbiologist *NW*
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

To: Velma Noble/Jacque McFarlane
Regulatory Management Branch I
Antimicrobials Division (7510C)

Thru: Emily Mitchell, M.S., Team Leader *Emily Mitchell 12/2/02*
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

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

Applicant: Reckitt Benckhiser Inc.
1655 Valley Road
Wayne, NJ 07474-9433

Formulation Label:

Active Ingredient(s)

n-Alkyl (50% C₁₄, 40% C₁₂, 10% C₁₆) dimethyl

benzyl ammonium chloride.....0.28%

Other ingredients.....99.72%

Total.....100.000%

I. Background:

The registrant has requested that the Agency review its decision regarding the

acceptance of efficacy data generated by testing to support the addition of label claims for the effectiveness of the product as a sanitizer against *Campylobacter jejuni*, *Escherichia coli*, and *Salmonella choleraesuis*. In a letter dated August 24, 2002 the Agency had required that claims for these organisms be removed from the label. The three documents (MRID Nos. 543676-03, -05, and -06) containing reports of the efficacy testing and the results obtained have been reevaluated by the Product Science Branch.

II. Comments and Recommendations:

1. The efficacy testing to demonstrate the effectiveness of the product against the three organisms listed above is acceptable.
2. The registrant may list those organisms along with others previously tested as those against which the product shows effectiveness as a sanitizer.
3. The proposed label claim is not acceptable. The claim that the product may be used for "disinfecting and sanitizing " floors has not been approved by the Agency and must be removed from the label.
4. To support the use of the product as a floor disinfectant and sanitizer, efficacy data must be submitted.
5. The label must also address the following Agency concerns which were listed previously in its August 2002 letter:
 - a. The label does not specify the approximate size of the surface area which one towelette is able to cover.
 - b. The label does not state when a new towelette is needed during the disinfecting/sanitizing process.
 - c. The registrant must submit efficacy data specifying the type of soil load used in testing which supports the use of this product on floor surfaces against grease, food particles, and grime. Serum is inappropriate for this use.
 - d. The ability of the towelette to deliver the quantity of liquid sufficient to maintain a wet surface for the entire required 10 minute contact time.
 - e. The ability of the product to be an effective sanitizer and disinfectant on various types of flooring materials (marble, wood, slate, ceramics) as well as vinyl.
6. The statement on Page 2 of the label "starts killing (bacteria) (germs) on contact" must be removed.
7. The statement of Page 5 of the label. "simply use a (Product Name) with your Swiffer sweeper, Pledge Grab-It sweeper..." must be removed from the label.