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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

December 10, 2001

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 777-81/ Lysol Brand Disinfectant Toilet Bowl Cleaner

DP Barcode: D275923
Case No.: 008311

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

Through: Emily Mitchell, Team Leader Emily Mitchell 12/11/01
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

To: Adam Heyward, PM 34 / Drusilla Copeland
Regulatory Management Branch II
Antimicrobials Division (7510C)

Applicant: Reckitt Benckiser, Inc.

Formulation From Label:

Active Ingredient(s)	% by wt
Hydrogen chloride	9.50
Inert Ingredient(s)	90.50
Total	100.00

I **BACKGROUND:** Reckitt Benckiser, Inc., has submitted a set of three antimicrobial efficacy studies to support their product, Lysol Brand Disinfectant Toilet Bowl Cleaner. The MRID Numbers are 454355-01 through -03. MRID Number 454355-02 was conducted by Reckitt & Colman's Microbiology Laboratory. This submission includes a label for EPA Reg. No. 777-81 dated 6/11/01.

The test material used in the study is identified as "Formula Number V15-1541". MRID Number 454355-02 identifies that test material as being EPA Reg. No. 777-81, the registration product.

II **Use Directions**

Lysol Brand Disinfectant Toilet Bowl Cleaner is designed to be a toilet bowl cleaner that can be an effective disinfectant without scrubbing. The label states: "Disinfects without scrubbing." "Kills bacteria in 30 seconds."

"To clean and disinfect follow these easy steps:

1. Flush first and remove excess dirt and grime before cleaning and disinfecting.
2. Wet all surface of bowl interior, including sides of bowl and under the rim, with at least 4 oz. of liquid (squeeze bottle approximately 15 seconds). Replace cap securely.
3. Let soak for at least 10 minutes. Do not close toilet lid.
4. Rinse brush in fresh water after use."

III **Agency Standards for Proposed Claims**

Two of the studies included in this submission are sanitizing tests. The standard test bacteria for sanitizing studies are Staphylococcus aureus ATCC 6538 and Klebsiella pneumoniae, aberrant, ATCC 4352. Enterobacter aerogenes (ATCC 13048 or 15038) may be substituted for K. pneumoniae. Each lot is to be used against 10 carriers for a total of 20 samples. Killing of the test microorganism on all carriers is required. Plate count data, on appropriate culture media, must be submitted on each test microorganism to disclose that a concentration of at least 10^4 microorganisms survive the carrier-drying step in order to provide meaningful results.

A third study in this submission is a virucidal test. For virucides whose use-directions identify the product as one intended for use upon dry, inanimate, environmental surfaces (such as floors, tables, cleaned and dried medical instruments, etc.), carrier methods, which are modifications of either the AOAC Use-Dilution Method (for liquid surface disinfectants) or the AOAC Germicidal

Spray Products Test (for surface spray disinfectants), must be used in the development of the virological data. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface (petri dish, glass slide, steel cylinder, etc.) for a specified exposure period at room temperature. The virus is then assayed by an appropriate virological technique. The protocol for the viral assay must provide the following information:

(i) The virus recovery from a minimum of 4 determinations per each dilution in the assay system (tissue culture, embryonated egg, animal infection, or whatever assay system is employed).

(ii) Cytotoxicity controls: The effect of the germicide on the assay system from a minimum of 4 determinations per each dilution.

(iii) The activity of the germicide against the test virus from a minimum of 4 determinations per each dilution in the assay system.

(iv) Any special methods which were used to increase the virus titer and to detoxify the residual germicide.

(v) The ID-50 values calculated for each assay.

(vi) The test results shall be reported as the reduction of the virus titer by the activity of the germicide (ID-50 of the virus control less the ID-50 of the test system), expressed as log10 and calculated by a statistical method (Reed and Muench, 1938; Litchfield and Wilcoxon, 1949; as examples).

(vii) For virucidal data to be acceptable, the product must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident (as in attached tables) at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. The calculated viral titers must be reported with the test results.

IV Comments on the Submitted Efficacy Studies

1. MRID Number 454355-01: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" by Karen. M. Ramm. ViroMed Biosafety Laboratories. Study ID Number 7984. Study Completion Date 2/16/2000.

   The purpose of this study was to test the virucidal effectiveness of "Formula Number V15-1541" against Rotavirus, Strain WA. The study included 10% Fetal Bovine Serum as an organic soil load. Films of virus were prepared by

spreading 0.2 mL of virus inoculum over three 100 x 15 mm sterile glass petri dishes. The inoculated films were then air-dried. For each lot of disinfectant, separate dried virus films were exposed to 2.0 mL of the use dilution (1:7.5) for 30 seconds at 26°C. Following exposure, the plates were scraped with a cell scraper to resuspend the contents of the plate. The virus-disinfectant mixture was then passed immediately through a Sephadex column in order to detoxify the mixture. The filtrate was then titered by serial dilution for infectivity.

2. MRID Number 454355-02: "Disinfectant Efficacy Testing Non-Food Contact Type Sanitizer Activity In The Presence of Organic Soil" by Diane Boesenberg. Reckitt & Colman, Microbiology Laboratory. Study ID Number M.S. #98.0142. Study Completion Date 12/16/99.

   This study was conducted to assess the ability of "Formula V15-1541" to sanitize inanimate, non-food contact surfaces that have been contaminated or inoculated with *Staphylococcus aureus* (ATCC 6538) or *Enterobacter aerogenes* (ATCC 13048). This study was conducted using *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048) as the standard test bacteria for general sanitization. Five percent Fetal Bovine Serum was added to the bacterial culture as a soil load. A 1" x 1" section of a sterile Petri dish was inoculated with 0.01 mL of cultures of the test bacteria. Each section of 1" x 1" Petri dish was treated with 5.0 mL of a 1:7.5 dilution of the product. Each Petri dish remained in contact with the test substance for 30 seconds at ambient room temperature (25.4-27.2°C). After treatment, 95-100 mL of neutralizing medium was poured onto each Petri dish. The Petri dishes were rinsed three times, each time the rinsate was run though a filter funnel unit. The filter was removed and placed onto a plate containing Typtic Soy Agar (TSA). The Colony Forming Units (CFU) which grew on the filters were counted and recorded.

3. MRID Number 454355-03: "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces" by Jolene R. Kington. ViroMed Biosafety Laboratories. Study ID Number 8495. Study Completion Date 2/25/2000 (Amended 3/14/2000).

   This study was conducted to determine the ability of "Formula Number V15-1541" to sanitize inanimate, non-food contact surfaces contaminated or inoculated with *Escherichia coli* 0157:H7 (ATCC 43888). Five percent Fetal Bovine Serum was added to the bacterial culture as a soil load. Sterile glass carriers were inoculated with 0.03 mL of a 48-hour culture of the test bacteria. For each batch of test substance, five inoculated carriers were placed into separate jars. Five mL of the diluted (1:7.5) test substance was added to the jars. Each carrier remained in contact with the test substance for 30 seconds at ambient room temperature (21°C). After treatment, 20 mL of neutralizing broth was poured into each jar. Thirty minutes after neutralizing the test substance, 1.0 mL and 0.1 mL aliquots of the neutralizer solution were plated on blood agar.

The Colony Forming Units (CFU) which grew on the filters were counted and recorded.

V Results

Table 1 (from MRID Number 454355-01)

MRID Number 454355-01			
Dilution	Virus Control	Rotavirus + Batch B7338-NJ2-1537-L3	Rotavirus + Batch B7202-NJ2-1315
Cell Control	0 0 0 0	0 0 0 0	0 0 0 0
10^{-1}	+ + + +	T T T T	T T T T
10^{-2}	+ + + +	T T T T	T T T T
10^{-3}	+ + + +	0 0 0 0	0 0 0 0
10^{-4}	+ + + +	0 0 0 0	0 0 0 0
10^{-5}	+ + + +	0 0 0 0	0 0 0 0
10^{-6}	+ O + O	0 0 0 0	0 0 0 0
10^{-7}	+ 0 0 0	0 0 0 0	0 0 0 0
10^{-8}	0 0 0 0	0 0 0 0	*0 0 0 0

+ = positive for test virus
0 = no test virus recovered and/or no cytotoxicity present
T = cytotoxicity present

* - This study shows complete inactivation of Rotavirus beyond the cytotoxic level.

MRID Number454355-02		
Organism	Test Material Batch Number	Percent Reduction in Bacterial Count
Staphylococcus aureus (ATCC 6538)	B7352-NJ2-1351-L3	> 99.9%
	B7202-NJ2-1315	> 99.9%
	B7338-NJ2-1573-L3	> 99.9%
Enterobacter aerogenes (ATCC 13048)	B7352-NJ2-1351-L3	> 99.9%
	B7202-NJ2-1315	> 99.9%
	B7338-NJ2-1573-L3	> 99.9%

MRID Number 454355-03		
Organism	Test Material Batch Number	Percent Reduction in Bacterial Count
Escherichia coli 0157:H7 (ATCC 43888)	1423 (B7338-NJ2-1537-L3)	> 99.9%
	1450 (B7352-NJ2-1351-L3	> 99.9%

VI Conclusions

1. MRID Number 454355-01: Under the conditions of this study, "Formula Number V15-1541" is an effective virucide against Rotavirus, Strain WA. MRID Number 454355-02 identifies the test material as being EPA Reg. No. 777-81.

2. MRID Number 454355-02: Under the conditions of this study, Formula V15-1541/ EPA Reg. No. 777-81 is an effective sanitizer.

3. MRID Number 454355-03: Under the conditions of this study, "Formula V15-1541" is an effective sanitizer of *Escherichia coli* 0157:H7 (ATCC 43888) contaminated/ inoculated surfaces.

VII Recommendations

Note: This submission includes a label for EPA Reg. No. 777-81 dated 6/11/01.

1. Under the sub-heading Disinfection Claims, the submitted label states:

   - Reduces 99.9% of germs without scrubbing.
   - Kills bacteria in 30 seconds

   These appear to be sanitization claims, not disinfection claims. The registrant should move these statements to a section other than the disinfection claims section.

2. The request to add labeling claims as a virucide against Rotavirus, Strain Wa, is approved.

3. The request to add labeling claims as a (general) sanitizer is approved.

4. The request to add labeling claims as a sanitizer of *Escherichia coli* 0157:H7 (ATCC 43888) contaminated surfaces is approved.

5. The submitted label uses the term "America's" in several places. On page 2 of the 6/11/01 label for 777-81, the following statements are printed:

   - "America's home and hospital disinfectant toilet bowl cleaner."
   - "Leaves [America's] toilet bowl sanitary."
   - "Leaves [America's] toilet bowl sanitized.

Such statements are an improper use of the phrase "America's", and are not allowed on the label of pesticide products.

6. The phrase "#1" angle neck bottle is not acceptable. The phrase/term "#1" is not allowed on pesticide product labels other than as a brand name.

7. The statement "Lysol Brand Disinfectant Toilet Bowl Cleaner's unique formula lets you just apply and walk away" is not acceptable. The label contains several statements saying or implying that this product can be used without scrubbing: "Disinfects without scrubbing", "Cleans without scrubbing" etc. All toilet disinfectants/ sanitizers are considered to require scrubbing. This statement conflicts with "Cleans without a lot of scrubbing" on page three. "Apply product, rinse, flush and repeat to eliminate viruses and bacteria" implies that this product may be use to disinfect the toilet bowl without scrubbing. All claims that state or otherwise imply that this product may be used to clean a toilet bowl without scrubbing must be removed.

8. Page one of the submitted label states: "heavy duty formula". The term "heavy duty" is not allowed on pesticide product labels.

9. Page two of the submitted label uses the term "powerful disinfectant". The term "powerful" is not acceptable on pesticide product labels.

10. The claim "kills illness causing germs" needs to be clarified by identifying the bacterium or virus that is being referred to.

11. Page 3 contains the statement "Leave on at least 30 seconds to [sanitize] [disinfect] 99.9% of bacteria in your bowl." This statement is not acceptable and must be removed. It implies that leaving the product on for 30 seconds would disinfect the toilet bowl.

12. The statement "Removes bacterial biofilm in your toilet" on page four must be removed.

13. Page four of the label contains several "Gold standard claims". The PM Team should determine if these statements are acceptable:

    a. "The gold standard in toilet bowl care."
    b. "Gold formula toilet cleaner."
    c. "Platinum formula toilet cleaner"
    d. "Supreme toilet bowl cleaning formula"
    e. "Premium toilet cleaner"
    f. "Gold care toilet cleaner"
    g. "Intensive care for the toilet"
    h. "Ultimate toilet bowl cleaning formula"

Federal Register Vol. 49, No. 188, §156.15 states: "Superlatives such as 'perfect,' 'paramount,' 'ultimate,' 'ideal,' and 'superior,'" are considered to be misleading with respect to a product.

14. The submitted label make antimicrobial efficacy claims against the following organisms:

    a. Poliovirus Type 1
    b. Hepatitis A

    These two viruses are not included on the 12/2/98 accepted label included with this submission. (No later approved labels were approved at the time of this review.) No data were included with this submission to support claims against Poliovirus Type 1 or Hepatitis A. The PM Team should decide if claims against these two viruses are acceptable.