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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

November 20, 2002

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 777-83 / Lysol Brand Disinfectant Bleach Plus

DP Barcode: D283735

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Applicant: Reckitt Benchkiser, Inc.

Formulation From Label:

Active Ingredient(s)	% by wt
Sodium hypochlorite	2
Inert Ingredient(s)	98
Total	100

1/21

I **BACKGROUND:** Reckitt Benckiser has submitted several studies in order to support the addition of sanitization, mildewstatic, virucidal and disinfectant claims to the label of their product, "Lysol Brand Disinfectant Bleach Plus". The submitted studies were conducted by Reckitt Benckiser, Inc., ViroMed Biosafety Laboratories and AppTec Laboratory Services. The MRID Numbers are 456880-01 through 456880-14. The submission, received by the Agency on 5/31/02, contains a transmittal letter from the registrant, a proposed label (EPA stamped 5/31/02) and fourteen antimicrobial efficacy studies.

Although reports 456880-01, -02 and several of the other reports do not state the relationship of the test material (434-128A) to EPA Registration Number 777-83, the bottom of the cover pages of MRID Number 456880-03 and -04 state that the study was conducted on 777-83.

II Use Directions

To clean and disinfect surfaces, apply full strength with a damp sponge or cloth onto surface to be cleaned, or apply product directly onto surface to be cleaned. Wipe clean and rinse.

To Sanitize/deodorize: Let stand for 30 seconds before wiping
To Disinfect/Deodorize: Let stand for 10 minutes before wiping

III Agency Standards for Proposed Claims

1 Non-Food Contact Sanitizers: (From DIS/TSS-10) To substantiate sanitizing claims for non-food contact surfaces (e.g., floors, walls, furnishings), the applicant must submit data to show that the product, when used as directed, will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The following protocol may be utilized:

A Test requirements. Three product samples, representing 3 different preparations, one of which is at least 60 days old, should be tested against each test bacterium on each test surface. The test bacteria are *Staphylococcus aureus* ATCC 6538 and *Klebsiella pneumoniae*, aberrant, ATCC 4352. *Enterobacter aerogenes* (ATCC 13048 or 15038) may be substituted for *K. pneumoniae*. The test surface(s) represent the type(s) of surfaces recommended for treatment on the label including, but not limited to, glass, metal, unglazed or glazed ceramic tile, porcelain, or vitreous china.

B Performance requirements. The results must show a bacterial reduction of at least 99.9% (3 log) over the parallel control count within 5 minutes. The starting inocula of the test microorganisms (for initial and subsequent challenges) must be of sufficient concentration to provide at least 104 survivors on the parallel control surface;

2 Disinfectants:

A General or broad-spectrum efficacy claims: Label claims of effectiveness as a "general disinfectant" or representations that the product is effective against a broad spectrum of microorganisms are acceptable if the product is effective against both Gram-positive and Gram-negative bacteria.

(1) Test requirements. Use the AOAC Use-Dilution Method or the AOAC Germicidal Spray Product Test as in (a)(I). Sixty carriers must be tested against each of both *S. choleraesuis* and *S. aureus* with each of 3 samples, representing 3 different batches, one of which is at least 60 days old. (120 carriers per sample; a total of 360 carriers.)
(2) Performance requirements. To support products represented in labeling as "disinfectants", killing on 59 out of each set of 60 carriers is required to provide effectiveness at the 95% confidence level.

B Hospital or medical environment efficacy claims:

(1) Label claims for use of disinfectants in Hospital or medical environments are acceptable only for those products that are effective for general or broad-spectrum disinfection and additionally against the nosocomial bacterial pathogen *Pseudomonas aeruginosa*.
(2) The performance requirements are the same as 1(B) above.

C Other microorganisms: Substantiated label claims of effectiveness of a disinfectant against specific microorganisms other than the designated test microorganism(s) are permitted, but not required, provided that the target pest is likely to be present in or on the recommended use areas and surfaces and thus may present a potential problem.

(1) Test requirements: Effectiveness of disinfectants against specific microorganisms other than those named in the AOAC Use Dilution Method, AOAC Germicidal Spray Products Test, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method (II. Confirmative In-Vitro Test), but not including viruses, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test as in (a)(I). Ten carriers must be tested against each specific microorganism with each of 2 samples, representing 2 different batches. (10 carriers per sample, a total of 20 carriers.)

(2) Performance requirements: 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.

3 Virucides: The Agency will accept adequate data developed by any virological technique which is recognized as technically sound, and which simulates to the extent possible in the laboratory the conditions under which the product is intended for use. 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. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. 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:

A 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).
B Cytotoxicity controls: The effect of the germicide on the assay system from a minimum of 4 determinations per each dilution.
C The activity of the germicide against the test virus from a minimum of 4 determinations per each dilution in the assay system.
D Any special methods which were used to increase the virus titer and to detoxify the residual germicide.
E The ID-50 values calculated for each assay.
F 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).
G For virucidal data to be acceptable, the product must substantiate 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.

Claims of virucidal activity for a product must be restricted to those viruses which have actually been tested. Separate studies on two batches of product are required for each virus.

IV Comments on the Submitted Efficacy Studies

1 MRID Number 456880-01: "Pesticide Assessment Guideline Subdivision G: Product Performance Section 91-2 (j) Sanitizers (for non-food contact surfaces) and DIS/TSS-10" by Pamela Stock. Reckitt Benkiser, Inc. Study Identification Number: M.S. # 2001-0116. Study Completion Date: 7/16/01.

This study was conducted to assess the ability of Lysol Brand Disinfectant Bleach Plus (EPA Registration Number 777-83) to act as a sanitizer of hard, non-porous, inanimate, non-food contact surfaces. The bacterial cultures used to inoculate the carriers included enough horse serum to act as a 5% organic soil load. The species used for this study were *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048). Test carriers (20 x 25 mm glass slides) were inoculated with 0.01 to 0.03 mL of the culture containing organic soil. For each batch of the test substance (710-051, 710-071 and 710-074), five contaminated carriers were each treated with 2 to 4 pumps/strokes of the test substance from 6 to 8 inches above the carrier. Batch 710-051 was over 60 days old at the time of testing. The treated slides remained in contact with the test substance for 30 seconds. After the 30-second contact period, each treated carrier was subcultured into 20 mL of neutralizing broth. One mL of the appropriate dilution was plated onto Tryptic Soy Agar. After incubation, results were read and recorded.

2 MRID Number 456880-02: "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces" by Jolene R. Kingston. ViroMed Biosafety Laboratories. Study ID Number: 8919. Study Completion Date: 7/25/2000.

This study was conducted to assess the ability of the test material to sanitize hard, non-porous, inanimate, non-food contact surfaces that are contaminated with *Enterobacter aerogenes* (ATCC 13048). An aliquot of Fetal Bovine Serum was combined with the broth culture to yield a 5% organic soil load. The carriers used for this study were glass slides. The test substance was prepared to make 1.5% solutions. The sterile glass carriers were inoculated with 0.03 mL of a 54-hour culture of *E. aerogenes.* After drying, all inoculated carriers/slides were transferred to individual sterile jars. For each of the three batches of test material, five inoculated carriers were exposed to 5.0 mL of the prepared test substance at staggered intervals. Each carrier remained in contact with the test substance for 10 seconds at 21°C. After treatment, 20 mL aliquots of neutralizer were added to each jar. Within 30 seconds after neutralizing the test

substance, 1.0 and 0.1 mL aliquots of neutralizer solution from each of the jars were plated in duplicate on blood agar plates.

3 MRID Number 456880-03: "Disinfectant Efficacy Testing In The Presence of Organic Soil" by Kyle T. Smith. Reckitt Benckiser, Inc. Study ID Number: M.S. #2001-0156. Study Completion Date: 11/12/2001.

This study was conducted to assess the ability of the test material to sanitize hard, non-porous, inanimate surfaces that have been contaminated with *Salmonella choleraesuis* (ATCC 10708). The bacterial cultures included enough horse serum to act as a 5% organic soil load. Test carriers (20 x 25 mm glass slides) were inoculated with 0.02 mL of the culture containing organic soil. For each batch of the test substance (710-071 and 710-074), five contaminated carriers were each treated with 2 to 4 pumps/strokes of the test substance from 6 to 8 inches above the carrier. The treated slides remained in contact with the test substance for 30 seconds at 18.6-19.7°C. After the 30-second contact period, each treated carrier was subcultured into 20 mL of neutralizing broth. Serial dilutions were performed with an appropriate broth. One mL of the appropriate dilution was plated onto Tryptic Soy Agar. After incubation, results were read and recorded.

4 MRID Number 456880-04: "Disinfectant Efficacy Testing In The Presence of Organic Soil" by Carolyn M. Mayerhauser. Reckitt Benkiser, Inc. Study ID Number: M.S. #2001-0157. Study Completion Date: 11/12/2001

This study was conducted to assess the ability of the test material to sanitize hard, non-porous, inanimate surfaces that have been contaminated with *Pseudomonas aeruginosa* (ATCC 15442). The bacterial cultures included enough horse serum to act as a 5% organic soil load. Test carriers (20 x 25 mm glass slides) were inoculated with 0.02 mL of the culture containing organic soil. For each batch of the test substance (710-051 and 710-071), five contaminated carriers were each treated with 2 to 4 pumps/strokes of the test substance from 6 to 8 inches above the carrier. The treated slides remained in contact with the test substance for 30 seconds at 21.0-21.4°C. After the 30-second contact period, each treated carrier was subcultured into 20 mL of neutralizing broth. Serial dilutions were performed with an appropriate broth. One mL of the appropriate dilution was plated onto Tryptic Soy Agar. After incubation, results were read and recorded.

5 MRID Number 456880-05: "Disinfectant Efficacy Testing In The Presence of Organic Soil" by Diane Boesenberg. Reckitt Benckiser, Inc. Study ID Number: M.S. #2001-0159. Study Completion Date: 11/01/01.

This study was conducted to assess the ability of the test material to sanitize hard, non-porous, inanimate surfaces that have been contaminated with

Escherichia coli (ATCC 43888). The bacterial cultures included enough horse serum to create a 5% organic soil load. Test carriers (20 x 25 mm glass slides) were inoculated with 0.03 mL of the culture containing organic soil. For each batch of the test substance (710-051 and 710-071), five contaminated carriers were each treated with 2 to 4 pumps/strokes of the test substance from 6 to 8 inches above the carrier. The treated slides remained in contact with the test substance for 30 seconds at 20.5-21.2°C. After the 30-second contact period, each treated carrier was subcultured into 20 mL of neutralizing broth. Serial dilutions were performed with an appropriate broth. One mL of the appropriate dilution was plated onto Tryptic Soy Agar. After incubation, results were read and recorded. This study was also intended to assay the test material against *Candida albicans*; however, that portion of the study failed. Efficacy data involving *Candida albicans* were not included in this report.

6 MRID Number 456880-06: "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Sanitizer" by Marc. S. Finley. ViroMed Laboratories, Inc. Study ID Number: 11013. Study Completion Date: 7/18/01.

This study was conducted to assess the ability of the test material to sanitize hard, non-porous, inanimate, non-food contact surfaces that are contaminated with *Trichophyton mentagrophytes* (ATCC 9533). Enough of an aliquot of Fetal Bovine Serum was combined with the broth culture to yield a 5% soil load. The carriers used for this study were glass slides. The test substance was used undiluted. The sterile glass carriers were inoculated with 0.03 mL of a conidial suspension of *Trichophyton mentagrophytes*. After drying, all inoculated carriers/slides were transferred to individual sterile jars. For each of the three batches of test material, five inoculated carriers were exposed to 5.0 mL of the prepared test substance at staggered intervals. Each carrier remained in contact with the test substance for 30 seconds at room temperature (24°C). After treatment, 45 mL aliquots of neutralizer were added to each jar. Within 10 minutes after neutralizing the test substance, 2.0 and 0.2 mL aliquots of neutralizer solution from each of the jars were plated in duplicate on potato dextrose agar plates.

7 MRID Number 456880-07: "Standard Test Method for Efficacy Sanitizers Recommended for Inanimate Non-Food Contact Surfaces" by Jennifer M. Price. ViroMed Laboratories, Inc. Project No.: 11457. Study Completion Date: 11/30/01.

This study was conducted to assess the ability of the test material to sanitize hard, non-porous, inanimate, non-food contact surfaces that are contaminated with *Listeria moncytogenes* (ATCC 19111). An aliquot of Fetal Bovine Serum was combined with the broth culture to yield a 5% soil load. The carriers used for this study were glass slides. The test substance was supplied and used as a

Ready-To-Use solution. The sterile glass carriers were inoculated with 0.01 mL of a culture of *Listeria monocytogenes* (ATCC 19111). After drying, all inoculated carriers/slides were transferred to individual sterile jars. For each of the three batches of test material, five inoculated carriers were exposed to 5.0 mL of the prepared test substance at staggered intervals. Each carrier remained in contact with the test substance for 30 seconds at room temperature (20°C). After treatment, 45 mL aliquots of neutralizer were added to each jar. Within 10 minutes after neutralizing the test substance, 2.0 and 0.2 mL aliquots of neutralizer solution from each of the jars were plated in duplicate on Tryptic Soy Agar with 5% Sheep Blood plates.

8 MRID Number 456880-08: "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces (Modification for Spray Product Application)" by Andrea J. Mesaros. AppTec Laboratory Services. Project No. 11870. Study Completion Date 2/8/02.

This study was conducted to assess the ability of the test material to sanitize hard, non-porous, inanimate, non-food contact surfaces that are contaminated with *Campylobacter jejuni* (ATCC 29428). An aliquot of Fetal Bovine Serum was combined with the broth culture to yield a 5% soil load. The carriers used for this study were 1 x 1 inch glass slides. The test substance was supplied and used as a Ready-To-Use solution. The sterile glass carriers were inoculated with 0.01 mL of a culture of *Campylobacter jejuni* (ATCC 29428). After drying, all inoculated carriers/slides were transferred to individual sterile jars. For each of the three batches of test material, five inoculated carriers were exposed to 5.0 mL of the prepared test substance at staggered intervals. Each carrier remained in contact with the test substance for 30 seconds at room temperature (19°C). After treatment, 45 mL aliquots of neutralizer were added to each jar. Within 10 minutes after neutralizing the test substance, 2.0 and 0.2 mL aliquots of neutralizer solution from each of the jars were plated in duplicate on Tryptic Soy Agar with 5% Sheep Blood plates.

9 MRID Number 456880-09: "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces" by Jennifer M. Price. ViroMed Laboratories, Inc. Project No.: 11456. Study Completion Date: 11/27/2001.

This study was conducted to assess the ability of the test material to sanitize hard, non-porous, inanimate, non-food contact surfaces that are contaminated with *Vibrio cholerae* (ATCC 11623). Enough Fetal Bovine Serum was combined with the broth culture to yield a 5% soil load. The carriers used for this study were glass slides. The product was applied as a Ready-To-Use spray. The sterile glass carriers were inoculated with 0.01 mL of a 48-hour culture of *Vibrio cholerae* (ATCC 11623). After drying, all inoculated carriers/slides were transferred to individual sterile jars. The test material was applied to each carrier

by spraying with 2 to 4 pumps of the test substance from a distance of 6 to 8 inches. Each carrier remained in contact with the test substance for 30 seconds at 20°C. After treatment, each carrier was transferred to a 20 mL aliquots of neutralizer. Within 10 minutes after neutralizing the test substance, 1.0 and 0.1 mL aliquots of neutralizer solution from each of the jars were plated in duplicate on blood agar plates (BAP).

10 MRID Number 456880-10: "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces" by Marc. S. Finley. Project Number: 10955. Study Completion Date: 10/5/01.

This study was conducted on *Aspergillus niger* (ATCC 16404). *Aspergillus niger* (ATCC 16404) is not a human health pathogen; therefore, this data is not required to be submitted or reviewed. This data will be retained in EPA files.

11 MRID Number 456880-11: "EPA Hard Surface Mildew-Fungistatic Test" by Marc S. Finley. ViroMed BioSafety Laboratories. Project Number 10773. Study Completion Date 8/20/01.

Mildew-Fungistat tests conducted on *Aspergillus niger* (ATCC 16404) such as this are not studies relating to human or animal pathogens. This study does not require a review by EET/PSB/AD scientists, but will be kept on file.

12 MRID Number 456880-12: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" by Mary Miller. ViroMed Laboratories, Inc. Project Number: 10940. Study Completion Date: 6/5/01.

This study was conducted to determine the ability to act as a virucide on surfaces contaminated with Rhinovirus, type 39, (ATCC VR-340) Strain 209. The stock virus culture contained 10% Fetal Bovine Serum (FBS) as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum over the bottoms of three separate 100 x 15 mm sterile glass petri dishes. The virus films were air-dried. The test substance was used undiluted, as received from the sponsor. The test material was applied to each carrier by spraying with 3 pumps/strokes of the test substance from a distance of 6 to 8 inches. Each carrier remained in contact with the test substance for 30 seconds at 20°C. The virus films were completely covered with the virucide. Following the exposure, the plates were scraped with a cell scraper. The virus disinfectant mixture was immediately added to 18.0 mL of neutralizer. To help reduce the cytotoxicity of the disinfectant to the indicator cell cultures, a 2.0 mL aliquot was removed from the disinfectant neutralizer mixture, for each batch of disinfectant, and passed through individual Sephadex columns. This was immediately followed by 10-fold serial dilutions. The total exposure period did not exceed 30 seconds. The dilutions were then assayed for infectivity. The filtrate was then titered by serial

dilution and assay for infectivity. The cell cultures employed MRC-5 (human embryonic lung) cells.

13 MRID Number 456880-13: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" by Mary J. Miller. ViroMed Biosafety Laboratories. Project Number: 10764. Study Completion Date: 5/15/01.

This study was conducted to determine the ability to act as a virucide on surfaces contaminated with Rotavirus, Strain WA. The stock virus culture contained 10% Fetal Bovine Serum (FBS) as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum over the bottoms of three separate 100 x 15 mm sterile glass petri dishes. The virus films were air-dried. The test material was diluted 1:38 for Batch 710-051 and 1:35.8 for Batch 710-074. For each batch of disinfectant, separate dried virus films were exposed to 2.0 mL of the use dilution. Each carrier remained in contact with the test substance for 30 seconds at 20°C. The virus films were completely covered with the virucide. Following the exposure, the plates were scraped with a cell scraper. The disinfectant neutralizer mixture, for each batch of disinfectant, was passed through individual Sephadex columns. This was immediately followed by 10-fold serial dilutions. The dilutions were then assayed for infectivity. The filtrate was then titered by serial dilution and assay for infectivity. The cell cultures employed MA-104 (Rhesus monkey kidney) cells.

14 MRID Number 456880-14: "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces" by Mary J. Miller. ViroMed Biosafety Laboratories. Project No.: 10765. Study Completion: 5/21/02.

This study was conducted to determine the ability to act as a virucide on surfaces contaminated with Human Immunodeficiency Virus type 1, Strain HTLV-III_B. The stock virus culture contained 10% Fetal Bovine Serum (FBS) as the organic soil load. Films of virus were prepared by spreading 0.2 mL of virus inoculum over the bottoms of three separate 100 x 15 mm sterile glass petri dishes. The virus films were air-dried. The test material was diluted 1:38 for Batch 710-051 and 1:35.8 for Batch 710-074. For each batch of disinfectant, separate dried virus films were exposed to 2.0 mL of the use dilution. Each carrier remained in contact with the test substance for 30 seconds at 21°C. The virus films were completely covered with the virucide. Following the exposure, the plates were scraped with a cell scraper. The disinfectant neutralizer mixture, for each batch of disinfectant, was passed through individual Sephadex columns. This was immediately followed by 10-fold serial dilutions. The dilutions were then assayed for infectivity. The filtrate was then titered by serial dilution and assay for infectivity. The cell cultures employed MT-2 cells (human CD4+ lymphocytes).

15 MRID Number 456880-15: "The Evaluation of the Efficacy of Formula 434-128A Against *Campylobacter jejuni* in the Presence of Filter Sterilized Reagent Water and a 5% Soil Load" by Jamie R. Lowe. ViroMed Laboratories, Inc. Project No.: 5381. Study Completion Date: 1/19/99.

This study was conducted to assess the ability of EPA Registration Number 777-83 to disinfectant hard, inanimate, non-porous surfaces that have been contaminated with *Campylobacter jejuni* (ATCC 29428). An aliquot of Fetal Bovine Serum was combined with the broth culture to yield a 5% soil load. the carriers used for this study were stainless steel penicylinders. Sterile cylinders were immersed for 15 minutes in a 48-54 hour old broth culture at a ratio of one carrier per one mL broth. The test solution was a 1:32 dilution of 777-83 in water. For each batch, ten contaminated and dried carriers were treated/ medicated individually transferred by hook needle to tubes containing 10 mL germicide at its use-dilution for three minutes at 20°C. The medicated carriers were neutralized by transferring to 10 mL of subculture medium. The culture medium used was Tryptic Soy Agar with 5% Sheep Blood (BAP).

V Results

Table 1, From MRID Number 456880-01: Sanitization of *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048) Contaminated Surfaces.

Staphylococcus aureus			
Batch	Log Average Count of Treated Carriers	Log Reduction	Conclusion
710-051	0	6.17	Pass
710-071	0	6.17	Pass
710-074	0	6.17	Pass
Control	6.17	n/a	n/a

Table 2, From MRID Number 456880-01: Sanitization of *Staphylococcus aureus* (ATCC 6538) and *Enterobacter aerogenes* (ATCC 13048) Contaminated Surfaces.

Enterobacter aerogenes			
Batch	Log Average Count of Treated Carriers	Log Reduction	Conclusion
710-051	0	5.82	Pass
710-071	0	5.82	Pass
710-074	0	5.82	Pass
Control	5.82	n/a	n/a

Table 3, From MRID Number 456880-02: Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces

Enterobacter aerogenes			
Batch	Log Average Count of Treated Carriers	Log Reduction	Conclusion
514-148	< 1.4	6.37	Pass
637-098	<1.4	6.37	Pass
613-117	<1.8	5.97	Pass
Control	7.77	n/a	n/a

Table 4, From MRID Number 456880-03: Sanitization of Non-Food Contact Surfaces Contaminated With *Salmonella choleraesuis* (ATCC 10708)

Salmonella choleraesuis (ATCC 10708)			
Batch	Log Average Count of Treated Carriers	Log Reduction	Conclusion
710-071	0	4.92	Pass
710-074	0	4.92	Pass
Control	4.92	n/a	n/a

Table 5, From MRID Number 456880-04: Sanitization of Non-Food Contact Surfaces Contaminated With *Pseudomonas aeruginosa* (ATCC 15442)

Pseudomonas aeruginosa (ATCC 15442)			
Batch	Log Average Count of Treated Carriers	Log Reduction	Conclusion
710-051	0.26	5.18	Pass
710-071	0.53	4.91	Pass
Control	5.37	n/a	n/a

Table 6, From MRID Number 456880-05: Sanitization of Non-Food Contact Surfaces Contaminated With *Escherichia coli* (ATCC 43888)

Escherichia coli (ATCC 43888)			
Batch	Log Average Count of Treated Carriers	Log Reduction	Conclusion
710-051	0.91	>4.33	Pass
710-071	0	>5.24	Pass
Control	>5.24	n/a	n/a

Table 7, From MRID Number 456880-06: Sanitization of Non-Food Contact Surfaces Contaminated With *Trichophyton mentagrophytes* (ATCC 9533)

Trichophyton mentagrophytes			
Batch	Log Average Count of Treated Carriers	Log Reduction	Conclusion
710-071	< 1.4	> 4.56	Pass
710-074	< 1.4	> 4.56	Pass
Control	5.96	n/a	n/a

Table 8, From MRID Number 456880-07: Sanitization of Non-Food Contact Surfaces Contaminated With *Listeria monocytogenes* (ATCC 19111)

Listeria monocytogenes (ATCC 19111)			
Batch	Log Average Count of Treated Carriers	Log Reduction	Conclusion
710-074	< 1.4	5.424	Pass
710-054	< 1.4	5.424	Pass
Control	6.824	n/a	n/a

Table 9, From MRID Number 456880-08: Sanitization of Non-Food Contact Surfaces Contaminated With *Campylobacter jejuni* (ATCC 29428)

Campylobacter jejuni (ATCC 29428)			
Batch	Log Average Count of Treated Carriers	Log Reduction	Conclusion
710-071	< 1.4	3.13	Passed
710-051	< 1.4	3.13	Passed
Control	4.53	n/a	n/a

Table 10, From MRID Number 456880-09: Sanitization of Non-Food Contact Surfaces Contaminated With *Vibrio cholerae* (ATCC 11623)

Vibrio cholerae (ATCC 11623)			
Batch	Log Average Count of Treated Carriers	Log Reduction	Conclusion
710-071	<1.3	>4.1	Passed
710-051	<1.3	>4.1	Passed
Control	5.4	n/a	n/a

Table 11, From MRID Number 456880-12: Virucidal Activity Against Rhinovirus type 39, ATCC VR-340, Strain 209 After a 30-Second Exposure to Registration Number 777-83.

Rhinovirus type 39, ATCC VR-340, Strain 209			
Contact Time	Results Lot No. 710-051	Results Lot No. 710-074	Dried Virus Control Count
30 seconds	Complete inactivation in the 10^{-2} to 10^{-8} dilutions. $\leq 10^{1.50}$ $TCID_{50}$/0.1mL	Complete inactivation in the 10^{-2} to 10^{-8} dilutions. $\leq 10^{1.50}$ $TCID_{50}$/0.1mL	$10^{5.5}$ (plate recovery)

Table 12, From MRID Number 456880-13: Virucidal Activity Against Rotavirus, Strain WA, After a 30-Second Exposure to Registration Number 777-83.

Rotavirus, Strain WA			
Contact Time	Results Lot No. 710-051	Results Lot No. 710-074	Dried Virus Control Count
30 seconds	Complete inactivation in the 10^{-1} to 10^{-8} dilutions. $\leq 10^{0.50}$ $TCID_{50}$/0.1mL	Complete inactivation in the 10^{-1} to 10^{-8} dilutions. $\leq 10^{0.50}$ $TCID_{50}$/0.1mL	$10^{5.75}$ (plate recovery)

Table 13, From MRID Number 456880-14: Virucidal Activity Against Human Immunodeficiency Virus type 1, Strain HTLV-III_B, After a 30-Second Exposure to Registration Number 777-83.

Human Immunodeficiency Virus type 1, Strain HTLV-III_B			
Contact Time	Results Lot No. 710-051	Results Lot No. 710-074	Dried Virus Control Count
30 seconds	Complete inactivation in the 10^{-1} to 10^{-7} dilutions. $\leq 10^{1.50}$ $TCID_{50}$/0.1mL	Complete inactivation in the 10^{-1} to 10^{-7} dilutions. $\leq 10^{1.50}$ $TCID_{50}$/0.1mL	$10^{5.0}$ (plate recovery)

Table 14, From MRID Number 456880-15: Disinfectant Ability of a 1:32 Dilution of 777-83 Against *Campylobacter jejuni* (ATCC 29428) After a Three-Minute Exposure at 20°C.

Campylobacter jejuni (ATCC 29428)				
		Number Positive / Number Tested		Numbers Control
Batch #	Test Run	Carriers	Neutralization Challenge	After Drying (cfu/carrier)
514-082A	1°	0/10	0/1	1.1×10^5
	2°	0/10	1/1	
514-082B	1°	0/10	0/1	
	2°	0/10	0/1	

VI Conclusions

1 MRID Number 456880-01: The submitted efficacy data support the use of the product, EPA Registration Number 777-83, as a non-food contact surface sanitizer when tested undiluted with 2 to 4 pumps of the test substance from 6 to 8 inches in the presence of organic soil (5% horse serum) on hard, non-porous, inanimate surfaces with a contact period of 30 seconds at room temperature (21.1-25.2°C).

2 MRID Number 456880-02: The submitted efficacy data support the use of the product, EPA Registration Number 777-83, as a non-food contact surface sanitizer of surfaces contaminated with *Enterobacter aerogenes* (ATCC 13048) when used at concentrations greater than, or equal to, 1.5% in the presence of organic soil (5% Fetal Bovine Serum) on hard, non-porous, inanimate surfaces with a contact period of 10 seconds at room temperature (21.1-25.2°C).

3 MRID Number 456880-03: The submitted efficacy data support the use of the product, EPA Registration Number 777-83, as a non-food contact sanitizer of *Salmonella choleraesuis* (ATCC 10708) contaminated surfaces when tested undiluted with 2 to 4 pumps of the test substance from 6 to 8 inches in the presence of organic soil (5% horse serum) on hard, non-porous, inanimate surfaces with a contact period of 30 seconds at room temperature (18.6-19.7°C).

4 MRID Number 456880-04: The submitted efficacy data support the use of the product, EPA Registration Number 777-83, as a non-food contact sanitizer of *Pseudomonas aeruginosa* (ATCC 15442) contaminated surfaces when tested undiluted with 2 to 4 pumps of the test substance from 6 to 8 inches in the presence of organic soil (5% horse serum) on hard, non-porous, inanimate surfaces with a contact period of 30 seconds at room temperature (21.0-21.4°C).

5 MRID Number 456880-05: The submitted efficacy data support the use of the product, EPA Registration Number 777-83, as a non-food contact sanitizer of *Escherichia coli* (ATCC 43888) contaminated surfaces when tested undiluted with 2 to 4 pumps of the test substance from 6 to 8 inches in the presence of organic soil (5% horse serum) on hard, non-porous, inanimate surfaces with a contact period of 30 seconds at room temperature (20.5-21.2°C).

6 MRID Number 456880-06: The submitted efficacy data support the use of the product, EPA Registration Number 777-83, as a non-food contact surface sanitizer when tested undiluted against *Trichophyton mentagrophytes* (ATCC 9533) in the presence of organic soil (5% Fetal Bovine Serum) on hard, non-porous, inanimate surfaces with a contact period of 30 seconds at room temperature (24°C).

7 MRID Number 456880-07: The submitted efficacy data support the use of the product, EPA Registration Number 777-83, as a non-food contact surface sanitizer when tested undiluted against *Listeria monocytogenes* (ATCC 19111) in the presence of organic soil (5% Fetal Bovine Serum) on hard, non-porous, inanimate surfaces with a contact period of 30 seconds at room temperature (20°C).

8 MRID Number 456880-08: The submitted efficacy data support the use of the product, EPA Registration Number 777-83, as a non-food contact surface sanitizer when tested undiluted against *Campylobacter jejuni* (ATCC 29428) in the presence of organic soil (5% Fetal Bovine Serum) on hard, non-porous, inanimate surfaces with a contact period of 30 seconds at room temperature (19°C).

9 MRID Number 456880-09: The submitted efficacy data support the use of the product, EPA Registration Number 777-83, as a non-food contact sanitizer of *Vibrio cholerae* (ATCC 11623) contaminated surfaces when tested undiluted with 2 to 4 pumps of the test substance from 6 to 8 inches in the presence of organic soil (5% horse serum) on hard, non-porous, inanimate surfaces with a contact period of 30 seconds at 20°C.

10 MRID Number 456880-12: The submitted efficacy data support the use of the product, EPA Registration Number 777-83, as a virucide of Rhinovirus type 39, ATCC VR-340, Strain 209 contaminated surfaces when tested undiluted with three pumps of the test substance from 6 to 8 inches in the presence of organic soil (10% Fetal Bovine Serum) on hard, non-porous, inanimate surfaces with a contact period of 30 seconds at 20°C.

11 MRID Number 456880-13: The submitted efficacy data support the use of the product, EPA Registration Number 777-83, as a virucide on Rotavirus, Strain WA, contaminated surfaces when diluted 1:38 or 1:35.8 on hard, non-porous, inanimate surfaces with a contact period of 30 seconds at 20°C in the presence of organic soil (10% Fetal Bovine Serum).

12 MRID Number 456880-14: The submitted efficacy data support the use of the product, EPA Registration Number 777-83, as a virucide on Human Immunodeficiency Virus type 1, Strain HTLV-III_B, contaminated surfaces when diluted 1:38 or 1:35.8 on hard, non-porous, inanimate surfaces with a contact period of 30 seconds at 21°C in the presence of organic soil (10% Fetal Bovine Serum).

13 MRID Number 456880-15: The study supports the use of Registration Number 777-83, when the product is applied at a dilution of 1:32, as a disinfectant on hard, non-porous, inanimate surfaces that have been contaminated with

Campylobacter jejuni (ATCC 29428) after a 3-minute exposure at 20°C in the presence of a 5% soil load.

VII Recommendations

1. The request to add additional label claims that 777-83 is an effective sanitizer on hard, non-porous, inanimate, non-food contact surfaces, when applied for 30 seconds at room temperature is acceptable. The non-food contact sanitization claim is also acceptable for the following specific organisms:

   Staphylococcus aureus (ATCC 6538)
   Enterobacter aerogenes (ATCC 13048)
   Salmonella choleraesuis (ATCC 10708)
   Pseudomonas aeruginosa (ATCC 15442)
   Escherichia coli (ATCC 4388)
   Trichophyton mentagrophytes (ATCC 9533)
   Listeria monocytogenes (ATCC 19111)
   Campylobacter jejuni (ATCC 29428)
   Vibrio cholerae (ATCC 11623)
   Aspergillus niger (ATCC 16404)

2. The request to add label claims that 777-83 is an effective virucide on hard, non-porous, inanimate, non-food contact surfaces after a 30-second exposure contaminated with the following viruses is acceptable:

   Rhinovirus type 39, Strain 209 (ATCC VR-340) - (undiluted)
   Rotavirus, Strain WA - (diluted 1:38 or 1:35.8)
   Human Immunodeficiency Virus type 1, Strain HTLV-III_B -(diluted 1:38 or 1:35.8)

3. The request to add label claims that 777-83 is an effective disinfectant of hard, non-porous, inanimate, non-food contact surfaces after a 3-minute exposure contaminated with *Campylobacter jejuni* (ATCC 29428) is acceptable.

4. The request to add label claims that 777-83 is an effective mildewstat against *Aspergillus niger* (ATCC 16404) is acceptable.

5. Page 2 of the submitted label states: "Kills (Eliminates) Salmonella choeraesuis ..." This should be changed to state: "Kills (Eliminates) Salmonella choleraesuis..."

6. Page 2 of the submitted label states: "Lysol Brand Foaming Disinfectant Bleach (This Product) meets Dilution efficacy test standards for Hospital type disinfection (Hospital Disinfectants)." This statement must be changed to:

"Lysol Brand Foaming Disinfectant Bleach (This Product) meets Dilution efficacy test standards for Hospital disinfection (Hospital Disinfectants)." The use of the phrase hospital **type** is unacceptable.

7. Page 3 of the submitted label states that this product kills "Rhinovirus Wa" and "Rotovirus 39". This should be changed to state that this product kills "Rhinovirus type 39" and Rotovirus Wa".

8. Page 3 of the submitted label states: "Rinse food contact surfaces with potable water." This statement implies that this product is approved for use as a food contact surface sanitizer. This product has *not* been approved as a food contact surface sanitizer. This statement must be removed.

9. Paragraph 2 of page 4 states that this product may be used on kitchen appliances. This should be revised to state that this product may be used on the **outside** of kitchen appliances. This applies to paragraph 2 and any other place on the product label.

10. Page 7, 4(a) of the submitted label lists several species of bacteria against which this product is claimed to be an effective sanitizer. The following must be removed from that list because the registrant has not submitted information to support sanitization claims against them:

    Streptococcus pyogenes *Klebsiella pneumoniae*
    Escherichia coli 0157:H7

    Labeling claims against these three organisms are not acceptable anywhere on the product label until AD/PSB/EET has approved data to support claims against these organisms.

11. Page 9 of the submitted label states that this product may be used as a disinfectant and/or sanitizer in kitchens and butcher shops. The label should include an asterisk by such statements and a claim that this product has not been approved for use on food-contact surfaces.

12. The product label should have separate and distinct directions for disinfection and sanitization.

13. Page 2 of the submitted label has the statements:

    A "Use regularly to help keep your home healthy." and
    B "Help keep your home a healthier place."

    These statements are inappropriate and must be removed.

13 Page 2 of the submitted label has the statement: "Safe for plumbing and septic systems." The use of the word "safe" is not acceptable for use on pesticide labels. The registrant must find some other wording to express this statement.

14 The bottom of page 8 of the submitted label states: "Helps protect you family from illness causing germs." This statement is inadmissible and must be removed.