UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

November 5, 2007

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 56392-8, Dispatch Cleaner Disinfectant Towel; DP Barcode: 342576

From: Tajah L. Blackburn, Ph.D., Microbiologist 11/6/07
Efficacy Evaluation Team
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Thru: Michele Wingfield, Chief
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Applicant: Caltech Industries, Inc.
Midland, MI 48642

Formulations from Label

Active Ingredient(s)	% by wt.
Sodium Hypochlorite.....	0.52%
Other Ingredients.....	99.48%
Total	100.00%

I BACKGROUND

The product, Dispatch Hospital Cleaner Disinfectant Towels with Bleach (EPA Reg. No. 56392-8), is a registered disinfectant (bactericide, virucide, fungicide) for use on hard, non-porous surfaces in institutional and hospital or medical environments. The applicant requested to amend the product registration to add claims for effectiveness as a disinfectant against *Acinetobacter baumannii*, *Enterobacter aerogenes*, *Escherichia coli* ESBL, *Klebsiella pneumoniae*, Influenza A virus, Canine parvovirus, Feline panleukopenia virus, Norovirus, and Rhinovirus. The label claims that the product is effective in "one-step" (i.e., effective in the presence of organic soil). Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, in Eagan, MN 55121.

This data package contained a letter from the applicant's representative to EPA (dated July 16, 2007), EPA Form 8570-1 (Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), eight studies (MRID 471863-01 through 471863-08) describing testing conducted on the "Dispatch" liquid, one study (MRID 471859-01) describing testing conducted on the "Dispatch" towels, Statements of No Data Confidentiality Claims for all nine studies, and the proposed label.

II USE DIRECTIONS

The product is designed for disinfecting hard, non-porous surfaces such as autoclaves, bed railings, blood glucose monitors, cabinets, carts, chairs, changing tables, counters, cribs, exam tables, external surfaces of ambulance equipment, exterior surfaces of diagnostic equipment, external surfaces of dialysis machines, external surfaces of mammography equipment, external surfaces of patient monitoring equipment, external surfaces of respiratory equipment, external surfaces of ultrasound transducers and probes, gurneys, IV poles, infant incubators and care cribs, phlebotomy trays, stretchers, tables, trash cans, and toys. The label indicates that the product may be used on hard, non-porous surfaces including: glass, glazed ceramic tile, glazed porcelain, painted surfaces, plastic, Plexiglas, sealed fiberglass, stainless steel, and vinyl. Directions on the proposed label provided the following information regarding use of the product as a disinfectant: Remove gross soil. Wipe surface with towel until completely wet. Allow surface to remain wet for 1 minute at room temperature (2 minutes for TB).

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Antimicrobial Products for Use on Hard Surfaces Using Pre-saturated or Impregnated Towelettes

Towelette products represent a unique combination of antimicrobial chemical and applicator, pre-packaged as a unit in fixed proportions. As such, the complete product, as offered for sale, should be tested according to the directions for use to ensure the product's effectiveness in treating hard surfaces. The standard test methods available for hard surface disinfectants and sanitizers, if followed exactly, would not closely simulate the way a towelette product is used. Agency guidelines recommend that a

simulated-use test be conducted by modifying the standard test methods. Agency guidelines further recommend that instead of spraying the inoculated surface of the carrier, the product should be tested by wiping the surface of the carrier with the saturated towelette, and then subculturing the slides after a specified holding time. Performance standards of the standard test methods must be met. These Agency standards are presented in EPA Pesticide Assessment Guidelines, Subdivision G, §91-2(h), Pre-saturated or impregnated towelettes; and the April 12, 2001 EPA Memorandum, Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes.

Disinfectants for Use on Hard Surfaces (Additional Bacteria)

Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required. In addition, plate count data must be submitted for each microorganism to demonstrate that a concentration of at least 10^4 microorganisms survived the carrier-drying step. These Agency standards are presented in DIS/TSS-1.

Virucides

The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. 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 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. These Agency standards are presented in DIS/TSS-7.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2.

IV SYNOPSIS OF SUBMITTED EFFICACY STUDIES

1. MRID 471863-01 "AOAC Germicidal Spray Method, Test Organism: *Escherichia coli* with extended spectrum beta-lactamase resistance (ESBL) (ATCC BAA-196)," for Dispatch Hospital Cleaner Disinfectant with Bleach, by Becky Lien. Study conducted at ATS Labs. Study completion date – May 4, 2007. Project Number A04648.

[Note: This efficacy study for the liquid product is being used to demonstrate efficacy of the towel product.]

This study was conducted against *Escherichia coli* ESBL (ATCC BAA-196). Two lots (Lot Nos. WF061130 and UF061109) of the product, Dispatch Hospital Cleaner Disinfectant with Bleach, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were sprayed (3 pumps) at staggered intervals at a distance of 6-8 inches from the carrier surface. Each carrier was exposed to the product for 1 minute at 21°C at 7% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 ml of Letheen Broth with 0.1% sodium thiosulfate to neutralize. After at least 30 minutes following the first transfer, the carriers were transferred from the primary subcultures into individual secondary subcultures containing 20 ml of Letheen Broth with 0.1% sodium thiosulfate. All subcultures were incubated for 48.5 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Note: The antimicrobial susceptibility pattern of *Escherichia coli* ESBL was verified using the AB BIODISK Etest Method. *Klebsiella pneumoniae* (ATCC 700603) and *Escherichia coli* (ATCC 35218) were the control organisms. The minimum inhibitory concentration (MIC) was read. The results confirmed the antibiotic resistance of *Escherichia coli* (ESBL). See pages 9, 16, and 17 of the laboratory report.

2. MRID 471863-02 "AOAC Germicidal Spray Method, Test Organism: *Enterobacter aerogenes* (ATCC 13048)," for Dispatch Hospital Cleaner Disinfectant with Bleach, by Becky Lien. Study conducted at ATS Labs. Study completion date – May 4, 2007. Project Number A04649.

[Note: This efficacy study for the liquid product is being used to demonstrate efficacy of the towel product.]

This study was conducted against *Enterobacter aerogenes* (ATCC 13048). Two lots (Lot Nos. WF061130 and UF061109) of the product, Dispatch Hospital Cleaner Disinfectant with Bleach, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were sprayed (4 pumps) at staggered intervals at a distance of 6-8 inches from the carrier surface. Each carrier was exposed to the product for 1 minute at 21°C at 4% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 ml of Letheen Broth with 0.1% sodium thiosulfate to neutralize. After at least 30 minutes following the first transfer, the carriers were transferred from the primary subcultures into individual secondary subcultures containing 20 ml of Letheen Broth with 0.1% sodium thiosulfate. All subcultures were incubated for 48 hours at 25-30°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

3. MRID 471863-03 "AOAC Germicidal Spray Method, Test Organism: *Acinetobacter baumannii* (ATCC 19606)," for Dispatch Hospital Cleaner Disinfectant with Bleach, by Becky Lien. Study conducted at ATS Labs. Study completion date – May 4, 2007. Project Number A04650.

[Note: This efficacy study for the liquid product is being used to demonstrate efficacy of the towel product.]

This study was conducted against *Acinetobacter baumannii* (ATCC 19606). Two lots (Lot Nos. WF061130 and UF061109) of the product, Dispatch Hospital Cleaner Disinfectant with Bleach, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were sprayed (3 pumps) at staggered intervals at a distance of 6-8 inches from the carrier surface. Each carrier was exposed to the product for 1 minute at 21°C at 6% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 ml of Letheen Broth with 0.1% sodium thiosulfate to neutralize. After at least 30 minutes following the first transfer, the carriers were transferred from the primary subcultures into individual secondary

subcultures containing 20 ml of Letheen Broth with 0.1% sodium thiosulfate. All subcultures were incubated for 49 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

4. MRID 471863-04 "AOAC Germicidal Spray Method, Test Organism: *Klebsiella pneumoniae* (ATCC 4352)" for Dispatch Hospital Cleaner Disinfectant with Bleach, by Becky Lien. Study conducted at ATS Labs. Study completion date – May 7, 2007. Project Number A04651.

[Note: This efficacy study for the liquid product is being used to demonstrate efficacy of the towel product.]

This study was conducted against *Klebsiella pneumoniae* (ATCC 4352). Two lots (Lot Nos. WF061130 and UF061109) of the product, Dispatch Hospital Cleaner Disinfectant with Bleach, were tested using the AOAC Germicidal Spray Products as Disinfectants Method as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. The product was received ready-to-use. Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass slide carriers were inoculated with 0.01 ml of a 48-54 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C at 40% relative humidity. For each lot of product, separate carriers were sprayed (3 pumps) at staggered intervals at a distance of 6-8 inches from the carrier surface. Each carrier was exposed to the product for 1 minute at 21°C at 3% relative humidity. Following exposure, the remaining liquid was drained off. Individual carriers were transferred to 20 ml of Letheen Broth with 0.1% sodium thiosulfate to neutralize. After at least 30 minutes following the first transfer, the carriers were transferred from the primary subcultures into individual secondary subcultures containing 20 ml of Letheen Broth with 0.1% sodium thiosulfate. All subcultures were incubated for 45.5 hours at 35-37°C. The subcultures were then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

5. MRID 471863-05 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Rhinovirus type 37," for Dispatch Hospital Cleaner Disinfectant with Bleach, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – May 9, 2007. Project Number A04665.

This study was conducted against Rhinovirus type 37 (Strain 151-1; ATCC VR-1147) using cultures of MRC-5 cells (ATCC CCL-171; propagated in-house) as the host system. Two lots (Lot Nos. WF061130 and UF061109) of the product, Dispatch Hospital Cleaner Disinfectant with Bleach, were tested according to ATS Labs Protocol No. SRC36010807.RHV.1 (copy provided). The product was received ready-to-use. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 54% relative humidity. For each lot of product, one dried virus film was sprayed (3 pumps) with the product at a distance of 6-8 inches from the carrier surface.

Each virus film was exposed to the product for 1 minute at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 10% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. MRC-5 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

6. MRID 471863-06 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Influenza A virus," for Dispatch Hospital Cleaner Disinfectant with Bleach, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – May 9, 2007. Project Number A04671.

[Note: This efficacy study for the liquid product is being used to demonstrate efficacy of the towel product.]

This study was conducted against Influenza A virus (Strain Hong Kong; ATCC VR-544) using cultures of Rhesus monkey kidney (RMK) cells (obtained from Viromed Laboratories, Inc., Cell Culture Division; maintained in-house) as the host system. Two lots (Lot Nos. WF061130 and UF061109) of the product, Dispatch Hospital Cleaner Disinfectant with Bleach, were tested according to ATS Labs Protocol No. SRC36010807.FLUA (copy provided). The product was received ready-to-use. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 55% relative humidity. For each lot of product, one dried virus film was sprayed (3 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each virus film was exposed to the product for 1 minute at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 1% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. RMK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

7. MRID 471863-07 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Canine Parvovirus," for Dispatch Hospital Cleaner Disinfectant with Bleach, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – May 9, 2007. Project Number A04647.

[Note: This efficacy study for the liquid product is being used to demonstrate efficacy of the towel product.]

This study was conducted against Canine parvovirus (Strain Cornell; ATCC VR-2017) using cultures of A-72 cells (canine tumor cells; ATCC CRL-1542; propagated in-house) as the host system. Two lots (Lot Nos. WF061130 and UF061109) of the product, Dispatch Hospital Cleaner Disinfectant with Bleach, were tested according to ATS Labs Protocol No. SRC36010807.CPV (copy provided). The product was received ready-to-use. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0-20.1°C at 46-50% relative humidity. For each lot of product, one dried virus film was sprayed (4 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each virus film was exposed to the product for 1 minute at 20.0-20.1°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 5% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. A-72 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. On the final day of incubation, a hemagglutination assay was performed on the cultures at 2-8°C. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

8. MRID 471863-08 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces, Virus: Feline Panleukopenia virus," for Dispatch Hospital Cleaner Disinfectant with Bleach, by Kelleen Gutzmann. Study conducted at ATS Labs. Study completion date – May 22, 2007. Project Number A04678.

[Note: This efficacy study for the liquid product is being used to demonstrate efficacy of the towel product.]

This study was conducted against Feline panleukopenia virus (Strain Philips-Roxane; ATCC VR-648) using cultures of feline kidney cells (CRFK cells; ATCC CCL-94; propagated in-house) as the host system. Two lots (Lot Nos. WF061130 and UF061109) of the product, Dispatch Hospital Cleaner Disinfectant with Bleach, were tested according to ATS Labs Protocol No. SRC36010807.FPLV (copy provided). The product was received ready-to-use. The stock virus culture was adjusted to contain 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were air-dried for 20 minutes at 20.0°C at 52% relative humidity. For

each lot of product, one dried virus film was sprayed (4 pumps) with the product at a distance of 6-8 inches from the carrier surface. Each virus film was exposed to the product for 1 minute at 20.0°C. After exposure, the plates were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 10% heat-inactivated fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. CRFK cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 14 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. On the final day of incubation, a hemagglutination assay was performed on the cultures at 2-8°C. Controls included those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: The applicant provided data for a failed trial set up on February 23, 2007. In that trial, the recoverable virus titer was less than 10^4. Thus, the test was invalid. These data were not used to evaluate efficacy of the test product. Testing was repeated on April 5, 2007. See Attachment I of the laboratory report.

9. MRID 471859-01 "Virucidal Efficacy of Pre-Saturated Towelettes for Hard Surface Disinfection, Virus: Rhinovirus type 37," for Dispatch Hospital Cleaner Disinfectant Towels with Bleach, by Mary J. Miller. Study conducted at ATS Labs. Study completion date – May 7, 2007. Project Number A04660.

This study was conducted against Rhinovirus type 37 (Strain 151-1; ATCC VR-1147) using cultures of MRC-5 cells (human embryonic lung cells; ATCC CCL-171; propagated in-house) as the host system. Two lots (Lot Nos. FG061115 and EG060929) of the product, Dispatch Hospital Cleaner Disinfectant Towels with Bleach, were tested according to ATS Labs Protocol No. SRC36010807.RHV.2 (copy provided). The product was received ready-to-use. The stock virus culture contained 5% fetal bovine serum as the organic soil load. Films of virus were prepared by spreading 0.2 ml of virus inoculum uniformly over the bottoms of separate sterile glass Petri dishes. The virus films were dried for 20 minutes at 20.0°C at 52% relative humidity. One saturated towelette was used to wipe the surface of each Petri dish. Each dish was wiped using two back and forth passes over each section of the dish, including the circumference, until the entire surface had been wiped and was completely wet. Each virus film was exposed to the product for 1 minute at 20.0°C. After exposure, 2.0 ml of test medium was added to each dish, and the dishes were scraped with a cell scraper to re-suspend the contents. The virus-disinfectant mixtures were passed through Sephadex columns, and diluted serially in Minimum Essential Medium supplemented with 10% fetal bovine serum, 10 µg/ml gentamicin, 100 units/ml penicillin, and 2.5 µg/ml amphotericin B. MRC-5 cells in multi-well culture dishes were inoculated in quadruplicate with 0.1 ml of the dilutions. The cultures were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the presence or absence of unspecified cytopathic effects, cytotoxicity, and viability. Controls included a system control (i.e., a clean towelette saturated with filter sterilized deionized water) and those for dried virus count, cytotoxicity, and neutralization. Viral and cytotoxicity titers were calculated by the method of Spearman Karber.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Population (CFU/ carrier)
		Lot No. WF061130	Lot No. UF061109	
471863-01	*Escherichia coli* ESBL	1°=0/10 2°=0/10	1°=0/10 2°=0/10	1.66×10^8
471863-02	*Enterobacter aerogenes*	1°=0/10 2°=0/10	1°=0/10 2°=0/10	7.1×10^8
471863-03	*Acinetobacter baumannii*	1°=0/10 2°=0/10	1°=0/10 2°=0/10	1.00×10^8
471863-04	*Klebsiella pneumoniae*	1°=0/10 2°=0/10	1°=0/10 2°=0/10	4.3×10^8

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1mL)
			Lot No. WF061130	Lot No. UF061109	
471863-05	Rhinovirus type 37	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{4.5}$
		$TCID_{50}$/0.1 ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
471863-06	Influenza A virus	10^{-1} to 10^{-8} dilutions	Complete inactivation	Complete inactivation	$10^{6.25}$
		$TCID_{50}$/0.1 ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
471863-07	Canine parvovirus	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{5.5}$
		$TCID_{50}$/0.1 ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
471863-08	Feline panleukopenia virus	10^{-1} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	$10^{4.5}$
		$TCID_{50}$/0.1 ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

MRID Number	Organism	Results			Dried Virus Control ($TCID_{50}$/0.1mL)
			Lot No. FG061115	Lot No. EG060929	
471859-01	Rhinovirus type 37	10^{-1} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	$10^{4.5}$
		$TCID_{50}$/0.1 ml	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, Dispatch Hospital Cleaner Disinfectant with Bleach, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute:

Acinetobacter baumannii	MRID 471863-03
Enterobacter aerogenes	MRID 471863-02
Escherichia coli ESBL	MRID 471863-01
Klebsiella pneumoniae	MRID 471863-04

Complete killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Dried carrier counts were at least 10^4 CFU/carrier. Neutralization confirmation testing showed positive growth of the microorganisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Antibiotic resistance was confirmed for *Escherichia coli* ESBL.

2. The submitted efficacy data support the use of the product, Dispatch Hospital Cleaner Disinfectant with Bleach, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute:

Canine parvovirus	MRID 471863-07
Feline panleukopenia virus	MRID 471863-08
Influenza A virus	MRID 471863-06
Rhinovirus type 37	MRID 471863-05

Recoverable virus titers of at least 10^4 were achieved. Cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested.

3. The submitted efficacy data (MRID 471859-01) support the use of the product, Dispatch Hospital Cleaner Disinfectant Towels with Bleach, as a disinfectant with virucidal activity against Rhinovirus type 37 on hard, non-porous surfaces in the presence of a 5% organic soil load for a contact time of 1 minute. A recoverable virus titer of at least 10^4 was achieved. Cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested.

VII RECOMMENDATIONS

Inert ingredient information may be entitled to confidential treatment

In response to chemistry comments from review conducted 11/9/05, SRC (consultants for Caltech Industries, Inc.) stated that "Dispatch Towel is produced with a [redacted] registered source of [redacted]. The CSF reflects a nominal level of 0.52% sodium hypochlorite which is consistent with the label declaration. The certified limits for sodium hypochlorite are 0.47% - 0.57% (N±10)."

1. The proposed label claims that the product, Dispatch Hospital Cleaner Disinfectant Towels with Bleach, is an effective "one-step" disinfectant against the following microorganisms on hard, non-porous surfaces for a contact time of 1 minute:

Acinetobacter baumannii
Enterobacter aerogenes
Escherichia coli ESBL
Klebsiella pneumoniae

Canine parvovirus
Feline panleukopenia virus
Influenza A virus
Rhinovirus

Data provided by the applicant support these claims. Efficacy data developed for the liquid product are being used to support efficacy of the towel product.

2. The proposed label claims that the product, Dispatch Hospital Cleaner Disinfectant Towels with Bleach, is an effective "one-step" disinfectant against Norovirus on hard, non-porous surfaces for a contact time of 1 minute. Data provided by the applicant support this claim. Efficacy data developed for the liquid product are being used to support efficacy of the towel product. In addition, as noted in an email message from EPA's Tajah Blackburn to the applicant's representative (dated October 17, 2006), "efficacy testing conducted against Rhinovirus using the towelette product is acceptable to bridge claims against Feline calicivirus, as both viruses are classified as small, non-enveloped viruses."

3. The label now claims efficacy for *Mycobacterium tuberculosis* (TB) in 2 minutes. The letter from the applicant's representative to the Agency (dated July 16, 2007) indicates that the Agency is currently reviewing a registration amendment to re-instate claims against *Mycobacterium tuberculosis*. To confirm this information, the efficacy reviewer attempted to research the product jacket. Due to complications with the system, the reviewer was unable to secure the product jacket. The registrant should submit documentation from the Agency reinstating *M. tuberculosis*. In the absence of documentation, this label claim is not acceptable.

4. The last-accepted label (and proposed label) claims that the product, Dispatch Hospital Cleaner Disinfectant Towels with Bleach, is an effective disinfectant against *Clostridium difficile* (vegetative) on hard, non-porous surfaces. All references to *Clostridium difficile* must be removed from the product label. The Agency is no longer accepting claims for effectiveness against *Clostridium difficile* (vegetative cells).

Note: The Agency has re-evaluated its acceptance of the *Clostridium difficile* (vegetative form) on previously accepted claims and requests for new claims. Peer-reviewed scientific literature and case studies have consistently demonstrated that the *Clostridium difficile* spore is the source of public-health concern. In light of scientific guidance and supporting documentation, the Agency is certain that claims against the vegetative form of *Clostridium difficile* are true statements, but are used in such a way as to give a false or misleading impression to the purchaser (40 CFR 156.10(a)(5)(vii)). The Agency considers antimicrobial pesticides to be unique because of the critical nature of the threat to public health that may result from ineffective use of the products due to

obsolete or misleading labeling. As a result, any reference to claims of effectiveness against *Clostridium difficile* (vegetative) OR *Clostridium difficile* (without having supporting data against *Clostridium difficile* spores) are unacceptable. To address the growing need for products in hospital/medical settings, the Agency is moving expeditiously to develop an appropriate test system and performance standards for *Clostridium difficile* spores.

5. The proposed label states that gloves should be worn when using the product [see "Directions for Use" section; "Canister Directions."] The proposed label needs to be revised to include the "Gloves should be worn" statement in the "Soft Pack Directions" and the "Individually Wrapped Pack Directions."

Note: Although the proposed label states that gloves should be worn, the "Precautionary Statements" section of the label does not mention that the user should avoid contacting skin with the product.

6. The following changes are required on the product label:

- On page 1 of the proposed label, change "*Enterococcus faecalis*" to read "*Enterococcus faecium*." ATCC 51559, *Enterococcus faecium* VRE, is listed on the Data Matrix.

- On page 3 of the proposed label, change "HVC" to "HCV"

7. Hepatitis A (HAV) is not classified as a bloodborne pathogen. Therefore, the inclusion of this virus in the Special Instructions section of the label is unwarranted.

8. Deodorizing instructions are required on the label, as the product makes claims to "deodorize...against odor-causing organisms....