UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 3, 2009

MEMORANDUM

Subject: Efficacy Review for Stepan Wipe Anywhere;
EPA Reg. No. 1839-EER; DP Barcode: D359751

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Applicant: Stepan Company
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Formulation from the Label:

Active Ingredient(s)	% by wt.
Didecyl dimethyl ammonium chloride	0.024%
Alkyl (40% C_{12}, 50% C_{14}, 10% C_{16}) dimethyl benzyl ammonium chloride	0.016%
Other Ingredients	99.960%
Total	100.000%

I. BACKGROUND

The product, STEPAN Wipe Anywhere (Registration Number 1839-EER), is a new product. The applicant requested to register the ready-to-use towelette product for use as a sanitizer, deodorizer, and cleaner on hard, non-porous surfaces in household, institutional, industrial, commercial, food processing, and animal care environments. The label claims that the product is an effective sanitizer in the presence of an organic soil load (5% blood serum) on food and non-food contact surfaces. Studies were conducted at Mycoscience Labs, Inc., located at 25 Village Hill Road, in Willington, CT 06279.

This data package contained a letter from the applicant to the Agency (dated December 1, 2008), two studies (MRIDs 476116-04 and -05), Statements of No Data Confidentiality Claims for both studies, and the proposed label.

II. USE DIRECTIONS

The product is designed for sanitizing hard, non-porous surfaces such as appliance interiors and exteriors, bathroom fixtures, bathtubs, booster chairs and seats, cabinets, car seats, carts, chairs, changing tables, computer keyboards, computers, countertops, cribs, cutting boards, desks, desktops, diaper pails, doorknobs, exercise machines, faucets, fax machines, floors, garbage cans, grocery cart handles, grocery carts, gym equipment, gymnastic equipment, headsets, high chair trays, high chairs, keyboards, personal protective safety equipment, railings, pet dishes and bowls, seats, shower stalls, showers, sinks, strollers, tables, tabletops, telephones, tiles, toilet seats, toilets, toys, trash cans, vanity tops, walls, and wrestling mats. The product label indicates that the product may be used on hard, non-porous surfaces including: Formica, glazed ceramic, glazed porcelain, glazed tile, fiberglass, glass, metal (i.e., stainless steel), and plastic (e.g., acrylic, vinyl). Directions on the proposed label provided the following information regarding use of the product:

> As a sanitizer on food contact surfaces: Prior to application, remove all gross food particles and soil from surfaces that are to be sanitized. Thoroughly wash or flush the surfaces with a good detergent, followed by a potable water rinse before applying product. For lightly soiled surfaces, use a first towelette to pre-clean the surface to be treated. One standard size 7" x 8" towelette will sanitize 72 square inches of surface. Allow the surface to remain wet for 60 seconds. Let surface dry. No final potable water rinse is allowed. Use a fresh towelette for each new surface to be sanitized.
>
> As a sanitizer on non-food contact surfaces: Prior to application, remove all gross soil from surfaces that are to be sanitized. Thoroughly wash or flush the surfaces with a good detergent, followed by a potable water rinse before applying product. For lightly soiled surfaces, use a first towelette to pre-clean the surface to be treated. One standard size 7" x 8" towelette will sanitize 72 square inches of surface. Allow the surface to remain wet for 30 seconds. Let surface dry. No rinsing is required.

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.

Sanitizing Rinses (For Previously Cleaned, Food Contact Surfaces)

Sanitizing rinses may be formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, or anionic detergent-acid formulations. The effectiveness of such sanitizing rinses for previously cleaned, food contact surfaces must be substantiated by data derived from the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method. Data from the test on 1 sample from each of 3 different product lots, one of which is at least 60 days old against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) are required. When the effectiveness of the product in hard water is made, all required data must be developed at the hard water tolerance claimed. Acceptable results must demonstrate a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported according to the actual count and the percentage reduction over the control. Furthermore, counts on the number controls for the product should fall between 75 and 125 x 10^6/mL for percent reductions to be considered valid. Label directions for use must state that a contact time of at least 1 minute is required for sanitization. A potable water rinse is not required (to remove the use solution for the treated surface) for products cleared for use on food contact surfaces under the Federal Food, Drug, and Cosmetic Act. Label directions must recommend a potable water rinse (to remove the use solution from the treated surface) under any other circumstances.

Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038).

Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Supplemental Recommendations

Antimicrobial agents which claim to be "one-step" cleaner-disinfectants, or cleaner-sanitizers, or agents to be used in the presence of organic soil, must undergo appropriate efficacy testing modified to include a representative organic soil of 5% blood serum. A suggested method to simulate antimicrobial treatment of dry inanimate surfaces is to add the blood serum 5% v/v (19mL bacterial inoculum with 1mL blood serum) to bacterial inoculum prior to carrier contamination and drying. Control data should be produced as described in Supplemental Recommendation 6 of DIS/TSS-2 to confirm the validity of this test with this modification. The suggested organic soil level is appropriate for simulation of lightly to moderately soiled surfaces. For highly soiled surfaces, a prior cleaning step should be recommended on the product label. A suggested procedure for incorporating organic soil load where the antimicrobial agent is not tested against a dry inanimate surface, such as the AOAC Fungicidal Test involves adding 5% v/v blood serum directly to the test solution (e.g., 4.75 ml test solution + 0.25 ml blood serum) before adding 0.5 ml of the required level (5 X 10^6 /ml) of conidia.

IV. SUMMARY OF SUBMITTED STUDIES

1. MRID 476116-04 "Stepan Company Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Food Contact Surfaces," Test Organisms: *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538) for Stepan Wipe Anywhere, by Richard Arsenault. Study conducted at Mycoscience Labs, Inc. Study completion date – November 19, 2008. Project Number 08-0668 STE.

This study was conducted against *Escherichia coli* (ATCC 11229) and *Staphylococcus aureus* (ATCC 6538). Five lots (Lot Nos. 3401-46, 3401-80, 3401-89, 3447-60, and 3447-61) of the product, Stepan Wipe Anywhere, were tested. The laboratory report referenced the Draft Interim EPA/AD Method Guidance #02 Dated April 12, 2001: Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes; and the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants Method (modified for inoculation onto test surfaces) as described in the AOAC Official Methods of Analysis, 17th Edition, 2000. At least one of the product lots tested (i.e., Lot No. 3401-46) was at least 60 days old at the time of testing. The product was received ready-to-use, as a pre-saturated towelette. A culture of each challenge microorganism was prepared in accordance with the published AOAC method. The cultures were standardized with a spectrometer so that the final surface inoculum was >7.5 x 10^7 CFU per 6" x 12" surface after drying. [The AOAC method states to standardize the inoculum to give an average of 10 x 10^9 organisms/mL.] Blood serum was added to each inoculum to achieve a 5% organic soil load. Three 6" x 12" glass surfaces (i.e., carriers) and three 6" x 12" textured high density polyethylene (HDPE) surfaces (i.e., carriers) per product lot per microorganism were tested. Each 6" x 12" carrier was inoculated with 0.125 mL of a 24-hour old suspension of the test organism. The inoculum was spread uniformly over the carrier. The carriers were dried for 30 minutes at 21-23°C (which differs from the Draft Interim Guidance of 40 minutes at 30-37°C). Each 6" x 12" carrier was wiped back and forth with one pre-saturated 7" x 8" wipe, using a reciprocal motion so that the entire inoculated surface was wiped

two times. The treated surface was allowed to remain exposed to the product for 30 seconds at 21-23°C at 36-50% relative humidity. Following exposure, each carrier was transferred to a sterile stomacher bag containing 1,000 mL of sterile AOAC neutralizer solution. [In addition, 30 seconds after wiping, each wipe was transferred to 200 mL of sterile AOAC neutralizer blank solution. The wipe in solution was immediately sonicated for 5 minutes, followed by manual agitation.] The carriers were immediately sonicated for 5 minutes, followed by manual agitation. A membrane filtration technique was used to determine surviving numbers of the challenge microorganisms. Ten mL and 100 mL aliquots of the carrier extracts [and 2 mL and 20 mL aliquots of the wipe extracts] were filtered through individual sterile bacterial retentive filters. The filters were rinsed with 50 mL of AOAC neutralizing solution. The filters were transferred to the surface of Tryptone Glucose Extract Agar plates containing 25 mL/L AOAC stock neutralizer solution. All plates were incubated for a minimum of 48 hours at 35-37°C. Following incubation, the plates were enumerated. Per the protocol, the product was also tested at a 60-second contact time. Controls included those for purity, sterility, parallel count, and neutralization effectiveness.

Note: Testing deviated from AOAC method specifications to allow for inoculation onto test surfaces. Testing deviated from the Draft Interim Guidance with regard to carrier drying. These deviations appear not to have adversely affected the test.

2. MRID 476116-05 "Stepan Company Efficacy Study of Single Use Impregnated Towelettes for Use as a Sanitizer for Non-Food Contact Surfaces," Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352) for Stepan Wipe Anywhere, by Richard E. Arsenault. Study conducted at Mycoscience Labs, Inc. Study completion date – November 19, 2008. Project Number 08-0888 STE.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three product lots (Lot Nos. 3401-46, 3447-60, and 3447-61) of the product, Stepan Wipe Anywhere, were tested. The laboratory report referenced the Draft Interim EPA/AD Method Guidance #02 Dated April 12, 2001: Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes; and DIS/TSS-10. At least one of the product lots tested (i.e., Lot No. 3401-46) was at least 60 days old at the time of testing. The product was received ready-to-use, as a pre-saturated towelette. A culture of each challenge microorganism was prepared in accordance with the published AOAC method (i.e., Method 960.09). The cultures were standardized with a spectrometer so that the final surface inoculum was >1.0 x 10^6 CFU per 6" x 12" surface after drying. Blood serum was added to each inoculum to achieve a 5% organic soil load. Three 6" x 12" glass surfaces (i.e., carriers) per product lot per microorganism were tested. Each 6" x 12" carrier was inoculated with 0.125 mL of a 24-hour old suspension of the test organism. The inoculum was spread uniformly over the carrier. The carriers were dried for 40 minutes at 20-24°C (which differs from the Draft Interim Guidance of 40 minutes at 30-37°C). Each 6" x 12" carrier was wiped back and forth with one pre-saturated 7" x 8" wipe, using a reciprocal motion so that the entire inoculated surface was wiped two times. The treated surface was allowed to remain exposed to the product for 30 seconds at 20-24°C at 32-42% relative humidity. Following exposure, each carrier was transferred to a sterile stomacher bag containing 1,000 mL of sterile AOAC neutralizer solution. [In addition, 30 seconds after wiping, each wipe was transferred to 200 mL of sterile AOAC neutralizer blank solution. The wipe in solution was immediately sonicated for 5 minutes,

followed by manual agitation.] The carriers were immediately sonicated for 5 minutes, followed by manual agitation. A membrane filtration technique was used to determine surviving numbers of the challenge microorganisms. Ten mL and 100 mL aliquots of the carrier extracts [and 2 mL and 20 mL aliquots of the wipe extracts] were filtered through individual sterile bacterial retentive filters. The filters were rinsed with 50 mL of AOAC neutralizing solution. The filters were transferred to the surface of Tryptone Glucose Extract Agar plates containing 25 mL/L AOAC stock neutralizer solution. All plates were incubated for a minimum of 48 hours at 35-37°C. Following incubation, the plates were enumerated. Per the protocol, the product was also tested at a 60-second contact time. Controls included those for purity, sterility, parallel count, and neutralization effectiveness.

Note: Testing deviated from the Draft Interim Guidance with regard to carrier drying. This deviation appears not to have adversely affected the test.

V. RESULTS

MRID Number	Organism	Lot No.	Total No. Surviving[1]	Microbes Initially Present	Percent Reduction
			(CFU/carrier)		
476116-04	*Escherichia coli*	3401-46	$<1.26 \times 10^2$	1.4×10^8	>99.999
	30 seconds	3401-80	$<4.33 \times 10^1$	1.4×10^8	>99.999
	Glass carrier	3401-89	5.57×10^2	8.1×10^7	99.999
	Escherichia coli	3401-80	2.53×10^2	8.3×10^7	99.999
	60 seconds	3401-46	$<1.00 \times 10^1$	8.3×10^7	>99.999
	Glass carrier	3401-89	$<7.00 \times 10^1$	8.3×10^7	>99.999
	Escherichia coli	3401-46	$<3.00 \times 10^1$	8.2×10^7	>99.999
	30 seconds	3401-80	2.20×10^2	8.2×10^7	99.999
	Textured HDPE carrier	3401-89	$<4.67 \times 10^1$	8.2×10^7	>99.999
	Escherichia coli	3401-46	$<2.00 \times 10^1$	1.0×10^8	>99.999
	60 seconds	3401-80	4.40×10^2	1.0×10^8	99.999
	Textured HDPE carrier	3401-89	$<1.33 \times 10^1$	1.0×10^8	>99.999
476116-04	*Staphylococcus aureus*	3401-46	1.87×10^2	2.6×10^8	99.999
	30 seconds	3401-80	$<2.33 \times 10^1$	2.6×10^8	>99.999
	Glass carrier	3401-89	1.80×10^2	2.6×10^8	99.999
	Staphylococcus aureus	3401-46	2.77×10^2	1.2×10^8	99.999
	60 seconds	3447-60	$<2.37 \times 10^2$	1.2×10^8	>99.999
	Glass carrier	3447-61	$<1.33 \times 10^1$	1.2×10^8	>99.999
	Staphylococcus aureus	3401-46	3.53×10^2	1.2×10^8	99.999
	30 seconds	3401-80	5.57×10^2	1.2×10^8	99.999
	Textured HDPE carrier	3401-89	4.27×10^2	1.2×10^8	99.999
	Staphylococcus aureus	3401-46	4.33×10^1	2.4×10^8	99.999
	60 seconds	3447-60	1.10×10^2	2.4×10^8	99.999
	Textured HDPE carrier	3447-61	3.13×10^2	2.4×10^8	99.999

[1]Average of the total CFU recovered of three replicates.

MRID Number	Organism	Lot No.	Total No. Surviving[1]	Microbes Initially Present	Percent Reduction
			(CFU/carrier)		
476116-05	*Klebsiella pneumoniae*	3401-46	$<1.43 \times 10^2$	2.0×10^7	>99.9
	30 seconds	3447-60	$<7.33 \times 10^1$	2.0×10^7	>99.9
	Glass carrier	3447-61	4.00×10^1	2.0×10^7	99.9
	Klebsiella pneumoniae	3401-46	$<4.67 \times 10^1$	1.7×10^7	>99.9
	60 seconds	3447-60	9.67×10^1	1.7×10^7	99.9
	Glass carrier	3447-61	$<1.33 \times 10^1$	1.7×10^7	>99.9
	Staphylococcus aureus	3401-46	$<4.00 \times 10^1$	6.5×10^7	>99.9
	30 seconds	3447-60	$<1.00 \times 10^1$	6.5×10^7	>99.9
	Glass carrier	3447-61	$<1.67 \times 10^1$	6.5×10^7	>99.9
	Staphylococcus aureus	3401-46	$<2.00 \times 10^1$	6.6×10^7	>99.9
	60 seconds	3447-60	1.90×10^2	6.6×10^7	99.9
	Glass carrier	3447-61	$<1.67 \times 10^1$	6.6×10^7	>99.9

[1]Average of the total CFU recovered of three replicates.

VI. CONCLUSIONS

1. The submitted efficacy data (MRID 476116-04) support the use of the towelette product, Stepan Wipe Anywhere, as a sanitizer against *Escherichia coli* and *Staphylococcus aureus* on hard, non-porous, food contact surfaces – glass and textured HDPE surfaces – in the presence of a 5% organic soil load for a 30-second contact time. A bacterial reduction of at least 99.999 percent over the parallel control was observed within 30 seconds. At least one of the product lots tested was at least 60 days old at the time of testing. Neutralization effectiveness testing showed positive growth of the microorganisms. Sterility controls did not show growth.

2. The submitted efficacy data (MRID 476116-05) support the use of the product, Stepan Wipe Anywhere, as a sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* on hard, non-porous, non-food contact surfaces in the presence of a 5% organic soil load for a 30-second contact time. A bacterial reduction of at least 99.9 percent over the parallel control was observed within 30 seconds. At least one of the product lots tested was at least 60 days old at the time of testing. Neutralization effectiveness testing showed positive growth of the microorganisms. Sterility controls did not show growth.

VII. RECOMMENDATIONS

1. The proposed label claims that the product, STEPAN Wipe Anywhere, is an effective **sanitizer** for use on pre-cleaned*, hard, non-porous, **food contact surfaces** against *Escherichia coli* and *Staphylococcus aureus* for a 60-second contact time. These claims are **acceptable** as they are supported by the submitted data.

*Note: Though label directions indicate surfaces are to be pre-cleaned, testing was performed in the presence of a 5% soil load.

2. The proposed label claims that the product, STEPAN Wipe Anywhere, is an effective **sanitizer** for use on pre-cleaned*, hard, non-porous, **non-food contact surfaces** against *Staphylococcus aureus* and *Klebsiella pneumoniae* for a 30-second contact time. These claims are **acceptable** as they are supported by the submitted data.

*Note: Though label directions indicate surfaces are to be pre-cleaned, testing was performed in the presence of a 5% soil load.

3. The proposed label claims that the product is an effective cleaner and deodorizer. The label must be revised to include complete directions for use of the product as a cleaner and deodorizer.

4. On page 2, it is inaccurate to say that the product "meets AOAC Germicidal and Detergent standards." The AOAC does not set standards. The product was tested in accordance with an AOAC methods and meets EPA's measurements of success for that test. This statement needs to be reworded.

5. The following revisions are required on the proposed label:

- On page 2 of the proposed label, it is stated that the product may be used to sanitize (plastic) (glazed) (finished) (wood) cutting boards. Because wood is a porous surfaces, change "(finished) (wood)" to read "(finished wood)."

- On page 5 of the proposed label, change "fiberglass" to read "sealed fiberglass."

- On page 10 of the proposed label, change the percentage of inert ingredients to read "99.960%."