



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 19, 2002

MEMORANDUM:

Subject: Efficacy Review of Lab Validation Data for "A Residual Self-Sanitizing Product"
Product Name, "Clorox 409-R" (Fresh Scent Clorox Disinfecting Spray)
EPA Reg. No. 5813-67
DP Barcode: D279708 & D281207
Case No.: 062667

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Applicant: Clorox Services Company
7200 Johnson Dr.
Pleasanton, CA 94558

Formulation:

| <u>Active Ingredient(s)</u> | <u>% by wt</u> |
|---|-----------------|
| Octyl decyl dimethyl ammonium chloride | 0.1890% |
| Diocetyl dimethyl ammonium chloride | 0.0945% |
| Didecyl dimethyl ammonium chlorides..... | 0.0945% |
| Alkyl dimethyl benzyl ammonium chlorides..... | 0.2520% |
| Ethanol..... | 65.0000% |
| <u>Inert Ingredients</u> | <u>34.3700%</u> |
| Total | 100.0000% |

I BACKGROUND:

The registrant, Clorox Services Company has submitted a independent lab validation data to substantiate the 24-hour residual self sanitizing claim for use on hard non-porous environmental surfaces which includes a more representative "wear component for high traffic residential uses. The development includes the use of "Real World" environmental data, based on consumer use patterns on frequently touched surfaces.

Clorox Disinfecting Spray contains a patented technology which delivers residual self-sanitization over 24 hours. ("Kills 99.9% of Bacteria for 24 hours.") Clorox obtained a registration from the Agency in April 1999 under the condition that Clorox develop an alternative protocol to test residual sanitization. The conditional registration expires April 2002. Clorox agreed to submit a revised 24-hour residual self sanitizing testing protocol which includes a more representative wear component for 'high traffic' residential uses. The 24-hour residual self sanitizing protocol and 'wear' component must also take into account any commercial, institutional, and industrial uses that may be added to this or any other product label.

II USE DIRECTIONS (24-Hour Sanitization Claims):

To sanitize non-food contact surfaces: Spray 6 to 10 inches from pre-cleaned surface for 3-4 seconds until thoroughly wet. Surface must remain wet for 10 minutes before air drying. Kills 99.9% of bacteria for 24 hours. This product continues to kill 99.9% of bacteria. Long lasting and/or 24 hour action. Kills or proven effective against 99.9% of *Escherichia coli* 0157:H7, *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Klebsiella pneumoniae* for 24 hours. Use throughout the house on hard, non-porous surfaces: (1) Homes: Garages and Basements; pet areas (cat litter boxes), doorknobs, telephones, walls, floors, stereo consoles, outside of washers/dryers/, laundry rooms, closets, lamps, desks, work benches, filing cabinets, patio furniture, light switch panels, damp storage areas, hard, non-porous furniture and/or chairs, cabinet door handles, dressing carts, storage areas, and kennels, (2) Kitchens: recycling bins, garbage cans, trash cans, waste baskets, trash compactors, under sinks, drain boards, faucets, doorknobs, walls, floors, faucet handles, cabinets, outside of refrigerators, outside of appliances and microwaves, (3) Bathrooms: clothes hampers, toilets, toilet seats, floor around toilets, toilet areas, faucets, doorknobs, bathtubs, showers, plastic shower curtains, walls, glazed tiles, shower doors, floors, medicine cabinets, counter tops, toilet handles, faucet handles, diaper pails, and tubs.

III AGENCY STANDARDS:

Historically, the guidance for products making label claims for residual self-sanitizing activity of dried chemical residues on hard inanimate surfaces has been geared toward treated surfaces which are likely to become wet and remain wet under normal conditions of use. However, product claims are now being expanded to include surfaces which may be dry and still capable of providing residual sanitizing activity. The

following steps were developed as an interim guidance to applicants for products which bear label claims for residual self-sanitizing activity of dried chemical residues on treated surfaces under normal conditions of use. Each test must include the following basic elements:

1. It must be based upon an adequately controlled in-use study or simulated in-use study employing as test microorganisms those target pathogens that are likely to be encountered in the environment in which the product is to be used. Data must be generated for three (3) batches, one of which is at least 60 days old, against each organism claimed. If the product is intended for hospital and other healthcare settings, *Pseudomonas aeruginosa* must be included as a test organism.
2. Inocula of the test microorganisms at a sufficient concentration to provide at least 10^4 survivors on the parallel control surface must be employed for initial and subsequent challenges.
3. The residue on the treated surface(s) must be activated in a manner and over an exposure period identical to the use pattern for which the product is intended.
4. A wear or abrasion component must be included in the testing of the product. This component should demonstrate the product's ability to withstand multiple periods of contact and its potential from removing the product from the surface. The amount of wear resistance that a product will be required to exhibit may vary considerably, depending on the use sites claimed and whether the use sites are in households or public facilities. The Gardner Abrasion Tester may be used to simulate the touch patterns expected in the various use sites.
5. Since it is intended that the treated surface will retain the residual activity after multiple challenges, quantitative bacteriological sampling must be conducted at frequent and regular intervals for the length of time claimed. The pattern for recontamination must be the same as those which are likely to be encountered under normal conditions of use.
6. The same type(s) of surface without the treatment must be employed in the test and inoculated in a manner and over an exposure period identical to the use pattern for which the product is intended. The same type of untreated surface(s) must also be used as appropriate controls.
7. The test surface should have an organic soil load applied to the surface prior to the initial treatment and challenge. All subsequent inoculum challenges should incorporate the same organic soil load.
8. The environmental conditions, such as relative humidity and temperature, employed in the test must also be reported; these must be the same as those which are likely to be encountered under normal conditions of use.

For residual self-sanitizing claims, it must be demonstrated that at least 99.9% reduction in the numbers of test microorganisms occurred on the treated surface(s) over that of the parallel control surfaces.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES:

Data Summary:

MRID No. 455513-01 - The submitted study was conducted by Marc S. Finley, ViroMed Laboratories, Inc., 6101 Blue Circle Drive, Minneapolis, MN 55343, report dated September 13, 2001. The product was tested for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces. The batches (7416-130-1 and 7416-130-2) were tested against *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), undiluted in the presence of an organic soil load (5% fetal bovine serum) at 21°C for.

MRID No. 455513-02 - The submitted study was conducted by Marc S. Finley, ViroMed Laboratories, Inc., 6101 Blue Circle Drive, Minneapolis, MN 55343, report dated September 12, 2001. The product was tested for Residual Self-Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces. The batches (7416-130-1 and 7416-130-2) were tested against *Klebsiella pneumoniae* (ATCC 4352) and *Staphylococcus aureus* (ATCC 6538), undiluted in the presence of an organic soil load (5% fetal bovine serum) at 21°C for.

MRID No. 455513-03 - The studies were conducted by Marc S. Finley, ViroMed Laboratories, Inc., 6101 Blue Circle Drive, Minnetonka, MN 55343, dated September 12, 2001. The submitted data was developed by the Residual Self Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces Test Method. The efficacy data submitted was conducted with batches (7416-130-1 and 7416-130-2) against *Staphylococcus aureus* (ATCC No. 6538) and *Klebsiella pneumoniae* (ATCC No. 4352), undiluted, in the presence of an organic soil load (5% bovine serum) at room temperature on polycarbonate surfaces.

MRID No. 455513-04 - The studies were conducted by Marc S. Finley, AppTec Laboratory Services, 2540 Executive Drive, St. Paul, MN 55120, dated November 8, 2001. The submitted data was developed by the Residual Self Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces Test Method. The efficacy data submitted was conducted with batches (7416-130-1 and 7416-130-2) against *Staphylococcus aureus* (ATCC No. 6538), undiluted, in the presence of an organic soil load (5% bovine serum) at room temperature on polycarbonate surfaces. **(stainless steel was the surface listed on the control plate count)

MRID No. 456035-01 - The studies were conducted by Jennifer M. Price, AppTec Laboratory Services, 2540 Executive Drive, St. Paul, MN 55120, dated January 28, 2002. The submitted data was developed by the Residual Self Sanitizing Activity of Dried Chemical Residues on Hard Nonporous Surfaces Test Method. The efficacy data submitted was conducted with batches (7893-174-A and 7893-174-B) against

Staphylococcus aureus (ATCC No. 6538), undiluted, in the presence of an organic soil load (5% bovine serum) at room temperature on stainless steel surfaces.

V RESULTS:

MRID No. 455513-01

Stainless Steel - 4.4×10^6 cfu/carrier

| Stainless Steel 4.4 x 10 ⁶ CFU/carrier | | | | | |
|---|----------------------|-------------------|---------|----------------------------|-------------|
| Sample ID: Batch #7416-130-1 | | | | | |
| Surviving CFU/surface | Test Organism | Log ₁₀ | Average | Geometric Mean CFU/carrier | % Reduction |
| Stainless A | <i>K. pneumoniae</i> | 1.65 | <1.87 | <74.13 | >99.9 |
| Stainless B | | 2.48 | | | |
| Stainless C | | 1.88 | | | |
| Stainless D | | <1.48 | | | |
| Sample ID: Batch #7416-130-2 | | | | | |
| Surviving CFU/surface | Test Organism | Log ₁₀ | Average | Geometric Mean CFU/carrier | % Reduction |
| Stainless A | <i>K. pneumoniae</i> | 3.35 | <2.96 | <912.01 | >99.9 |
| Stainless B | | 1.65 | | | |
| Stainless C | | 5.37 | | | |
| Stainless D | | <1.48 | | | |

Due to failure of the Neutralization Confirmation, the efficacy data for *Staphylococcus aureus* was invalid, and was not repeated per Sponsor's request.

MRID No. 455513-02Glass - 2.1×10^6 cfu/carrier (*Staphylococcus aureus*)Glass - 6.2×10^6 cfu/carrier (*Klebsiella pneumoniae*)

| | | | | | |
|------------------------------|---------------|-------------------|---------|----------------------------|-------------|
| Sample ID: Batch #7416-130-1 | | | | | |
| Surviving CFU/surface | Test Organism | Log ₁₀ | Average | Geometric Mean CFU/carrier | % Reduction |
| Glass A | K. pneumoniae | 1.88 | <1.93 | <85 | >99.9 |
| Glass B | | 1.78 | | | |
| Glass C | | 2.59 | | | |
| Glass D | | <1.48 | | | |
| Sample ID: Batch #7416-130-2 | | | | | |
| Surviving CFU/surface | Test Organism | Log ₁₀ | Average | Geometric Mean CFU/carrier | % Reduction |
| Glass A | K. pneumoniae | <1.48 | <2.11 | <1.29 | >99.9 |
| Glass B | | <1.48 | | | |
| Glass C | | 2.65 | | | |
| Glass D | | 2.89 | | | |
| Sample ID: Batch #7416-130-1 | | | | | |
| Surviving CFU/surface | Test Organism | Log ₁₀ | Average | Geometric Mean CFU/carrier | % Reduction |
| Glass A | S. aureus | 3.20 | 3.10 | 1.3 x 10 ³ | >99.9 |
| Glass B | | 3.08 | | | |
| Glass C | | 3.04 | | | |
| Glass D | | 3.08 | | | |
| Sample ID: Batch #7416-130-2 | | | | | |
| Surviving CFU/surface | Test Organism | Log ₁₀ | Average | Geometric Mean CFU/carrier | % Reduction |
| Glass A | S. aureus | 3.34 | 3.02 | 1.0 x 10 ³ | >99.9 |
| Glass B | | 3.18 | | | |
| Glass C | | 2.65 | | | |
| Glass D | | 2.91 | | | |

MRID No. 455513-03Polycarbonate - 2.1×10^8 cfu/carrier (*Staphylococcus aureus*)Polycarbonate - 5.4×10^8 cfu/carrier (*Klebsiella pneumoniae*)

| Sample ID: Batch #7416-130-1 | | | | | |
|------------------------------|---------------|-------------------|---------|----------------------------|-------------|
| Surviving CFU/surface | Test Organism | Log ₁₀ | Average | Geometric Mean CFU/carrier | % Reduction |
| Polycarbonate A | S. aureus | 3.66 | 3.52 | 3.3 x 10 ³ | 99.8 |
| Polycarbonate B | | 3.43 | | | |
| Polycarbonate C | | 3.38 | | | |
| Polycarbonate D | | 3.59 | | | |
| Sample ID: Batch #7416-130-2 | | | | | |
| Surviving CFU/surface | Test Organism | Log ₁₀ | Average | Geometric Mean CFU/carrier | % Reduction |
| Polycarbonate A | S. aureus | 3.57 | 3.54 | 3.5 x 10 ³ | 99.8 |
| Polycarbonate B | | 3.66 | | | |
| Polycarbonate C | | 3.54 | | | |
| Polycarbonate D | | 3.40 | | | |
| Sample ID: Batch #7416-130-1 | | | | | |
| Surviving CFU/surface | Test Organism | Log ₁₀ | Average | Geometric Mean CFU/carrier | % Reduction |
| Polycarbonate A | K. pneumoniae | 3.61 | 3.13 | 1.3 x 10 ³ | 99.9 |
| Polycarbonate B | | 2.56 | | | |
| Polycarbonate C | | 2.98 | | | |
| Polycarbonate D | | 3.36 | | | |
| Sample ID: Batch #7416-130-2 | | | | | |
| Surviving CFU/surface | Test Organism | Log ₁₀ | Average | Geometric Mean CFU/carrier | % Reduction |
| Polycarbonate A | K. pneumoniae | 1.88 | 2.42 | 2.6 x 10 ² | 99.9 |
| Polycarbonate B | | 2.18 | | | |
| Polycarbonate C | | 2.32 | | | |
| Polycarbonate D | | 3.31 | | | |

MRID No. 455513-04Stainless Steel - 2.9×10^6 cfu/carrier

| Sample ID: Batch #7416-130-1 | | | | | |
|------------------------------|---------------|-------------------|---------|----------------------------|-------------|
| Surviving CFU/surface | Test Organism | Log ₁₀ | Average | Geometric Mean CFU/carrier | % Reduction |
| Polycarbonate A | S. aureus | 3.32 | 3.46 | 2.9 x 10 ³ | 99.9 |
| Polycarbonate B | | 3.41 | | | |
| Polycarbonate C | | 3.49 | | | |
| Polycarbonate D | | 3.60 | | | |

| Sample ID: Batch #7416-130-2 | | | | | |
|------------------------------|---------------|-------------------|---------|----------------------------|-------------|
| Surviving CFU/surface | Test Organism | Log ₁₀ | Average | Geometric Mean CFU/carrier | % Reduction |
| Polycarbonate A | S. aureus | 3.20 | 3.23 | 1.7 x 10 ³ | 99.9 |
| Polycarbonate B | | 3.26 | | | |
| Polycarbonate C | | 3.11 | | | |
| Polycarbonate D | | 3.36 | | | |

MRID No. 456035-01Stainless Steel - 1.6×10^6 cfu/carrier

| Sample ID | Surface | Log ₁₀ | Average | Geometric Mean | % Reduction |
|------------|-------------|-------------------|---------|----------------|-------------|
| 7893-174-A | Stainless A | 2.22 | 1.74 | 55 | 99.9 |
| | Stainless B | 1.78 | | | |
| | Stainless C | 1.18 | | | |
| | Stainless D | 1.78 | | | |
| 7893-174-B | Stainless A | 2.02 | 1.76 | 58 | 99.9 |
| | Stainless B | 1.48 | | | |
| | Stainless C | 2.35 | | | |
| | Stainless D | 1.18 | | | |

VI CONCLUSIONS:

When tested undiluted in the presence of a 5% organic soil load, the product showed effectiveness as a residual self sanitizer against *Staphylococcus aureus* and *Klebsiella pneumoniae* on stainless steel, glass, and polycarbonate surfaces for a 24 hour period. Clarification is need for MRID No. 455513-04, the results show stainless steel as the surface for the control plate counts and calculated control results, however, the final calculated results show polycarbonate as the surface.