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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 19, 2002

MEMORANDUM:

Subject: Protocol Efficacy Review of Test Method for "A Residual Self-Sanitizing Product"
Product Name, "Clorox 409-R" (Fresh Scent Clorox Disinfecting Spray)
EPA Reg. No. 5813-67
DP Barcode: D279335
Case No.: 062667

From: Emily Mitchell, M.S., Team Leader Emily Mitchell 3/20/02
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Michele E. Wingfield, Chief Michele E. Wingfield
Product Science Branch
Antimicrobials Division (7510C)

To: Laura Morris-Bailey, Special Assistant
Antimicrobials Division (7510C)

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

Formulation:

Active Ingredient(s)	% by wt
Octyl decyl dimethyl ammonium chloride	0.1890%
Dioctyl dimethyl ammonium chloride	0.0945%
Didecyl dimethyl ammonium chlorides.....	0.0945%
Alkyl dimethyl benzyl ammonium chlorides.....	0.2520%
Ethanol.....	65.0000%
Inert Ingredients	34.3700%
Total	100.0000%

I **BACKGROUND:**

The registrant, Clorox Services Company has submitted a revised protocol 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.

The 'wear' component of the original protocol was intended to simulate the effects of normal handling of a household surface and consisted of two parts. Wet wear was achieved by spraying the test surfaces with five pumps of water from a calibrated trigger spray bottle and then allowing the test surfaces to dry. The mechanical wear was obtained by the way the pressure exerted while spreading the inoculum over the test surface with a disposable sterile hockey stick inoculating needle. Other important aspects of the original protocol, such as intermittent inoculations and a 24-hour testing period, need to be maintained in the new protocol. In addition, Clorox and the Agency agreed that the revised protocol must use equipment that is affordable and readily available. There must be intra- and inter-laboratory reproducibility and the protocol must maintain efficient time and resource utilization. Clorox instituted a final important aspect to the new protocol. Clorox maintains that the protocol results must correlate to performance on actual "high-traffic" surfaces found in the home. In other words, a pass/fail result using the new protocol must reflect the benefit, or lack thereof, of product usage on a home surface.

This is a secondary review based on the recommendations from an expert panel and Agency microbiologists. The panel was provided with the protocol, a label, efficacy data, a summary of a meeting between the Agency and registrant, and a copy of a presentation made by the registrant dated July 27, 2000.

II **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 microorgansims 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.

III SUMMARY OF REVISIONS TO ORIGINAL PROTOCOL:

Many aspects of the original protocol, Clorox SOP #001-133-00, were maintained in this revised protocol. Both protocols incorporated inoculations and were conducted over a 24-hour period. An initial inoculation of the test surfaces was added to the new protocol to simulate a clean, but not necessarily disinfected surface in the home. However, the developmental focus for the revised protocol was to incorporate a more rigorous system of wear which would better replicate high traffic/high wear surfaces in the home.

Abrasion Tester-The Gardner-Abrasion Tester was used to simulate wiping to remove any film, soil, or other substance from a test surface so the linear abrasion applied is quite rigorous. Although, the forces associated with linear abrasion are different than those associated with gripping and pressing, the Gardner Abrasion tester was the best choice to incorporate reliable, consistent wear into the protocol. Preliminary abrasion tester parameters were set. A range of weights for the abrasion boat, which moves across the test surface were examined between 500 and 1500 grams. This range simulates the forces determined in the laboratory for scrubbing, finger pressing, and doorknob turning. The rate for motion of the sled was set so that approximately 1-4 seconds of abrasion occurred on the test surfaces. Again, this time period was measured in the laboratory as the approximate hand-to-surface time needed for turning a doorknob, using a faucet handle, etc. The sled is covered with a cotton clean room wipe covering a soft foam wipe. The cotton wipe has no additional chemicals in the cloth and is non-directional for ease of use. The foam simulates the soft feel of fingers. Finally, for wet wear, the cloth-covered sled has been misted with water and then used to wear the surface. These parameters constituted a starting place for development.

Test Surfaces-Originally, Clorox SOP #001-133-00 used ceramic tiles, however, it was found that the quality of tiles varies greatly, and the results were scattered and not reproducible. A variety of surfaces were tested, and three test surfaces were selected. The surfaces were chosen for the following reasons:

- Glass Microscope Slides-Glass was used as an industry standard in many testing protocols, and has similar surface characteristics as the ceramic tile.
- Mirrored Stainless Steel-Its surface characteristics are similar to that of the chrome surfaces found in many home, but it is more readily available as a test surface. Plus, stainless steel is also commonly found in households.
- Polycarbonate-Polypropylene (Trashcans, etc.), High/Low density Polyethylene (Trashcans), Polycarbonate (Appliances), and Acrylonitirile Butadiene Styrene (Telephones) were examined. The polyethylene available for testing was too soft and porous to use as a test surface. The other plastics all gave similar results, and polycarbonate was selected due to its ease of use and availability.

Once the test surface type had been selected and the abrasion tester shown to be reproducible, the complexity of the protocol was increased. The initial inoculation and intermittent inoculations were returned to the testing procedure. Finally, the 24-hour time bracket for testing was reinstated. The protocol parameters were adjusted until the results of the use of the Abrasion tester roughly corresponded to that of the environmental surface testing. "Curves" were generated which could be used to determine the exact number of passes to correlate to the environmental data.

IV 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.

V COMMENTS ON THE PROPOSED REVISED PROTOCOL(S):

The proposed testing protocol is aimed at determining the efficacy of a 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 data thus far presented to the Agency by the applicant suggests that the product is efficacious and reproducible under certain selected test conditions. However, additional changes/modifications are required to the protocol in order to provide evidence of the product's efficacy for household, commercial, institutional or industrial use.

Household Use:

1. The 24 touches as a benchmark for the worse case scenario is a bit conservative. Although, the Clorox Company claimed that this information was the result of a consumer usage habits survey, only a brief summary of the results was included in the protocol package. The Agency does not know the demographic of the people who were surveyed, or the size of the household surveyed. By observation, the handling of faucets is usually a two-touch

process. After the faucet is turned on, the hand releases the faucet and then proceeds to other activities like washing hands, or cleaning a fruits or vegetables. After the washing/rinsing activity is finished, the hand is returned to the faucet to turn it off. Only when the user is trying to obtain a small amount of water from the faucet is the turning on and off conducted in one continuous touch. Therefore, the assumption for this exercise would be that every activity involving the kitchen faucet would be a two touch process. The Agency estimates a minimum of 48 touches on a kitchen faucet in 24 hours in a household for a family of four people would double the amount of touches from Clorox's survey. The registrant should increase the minimum wearing from 6 cycles to 12 cycles, or repeat the consumer usage habit survey to better define the worse case usage and modify the wearing protocol accordingly.

2. Reduce the contact time of the final inoculum from 10 minutes to 5 minutes to better equate the residual data with the non-residual sanitizer data for non-food contact surfaces unless clarified on the label that 10 minutes contact time required for residual action to reduce bacteria by 99.9%.

Industrial/Institutional Use:

The protocol could be modified quite easily to evaluate the application of the product for industrial or institutional use. The registrant should obtain similar environmental data on use patterns in the various settings prior to modifying the protocol. It would be predicted that there would be much higher consumer contact with surfaces in these institutional environments and also a greater risk of reinoculation of surfaces. Use patterns must be determined before an appropriate number of additional cycles and reinoculations of organisms can be incorporated into a modified protocol for institutional use.

1. The minimum survivors on the control surfaces should be increased to 10^6 cfu in order for the study to be acceptable for commercial/institutional use.

2. It would be appropriate to include additional test organisms that are present in hospital environments, such as *Pseudomonas aeruginosa*.

3. Depending on the use site and label claims, the test protocol should include representative viruses when a virucidal claim is made on the label.

VI OTHER RECOMMENDATIONS AND LABELING COMMENTS:

The label should indicate not to wipe or clean the treated surface if the 24-hour residual sanitizer claim is expected to be maintained.

VII CONCLUSIONS:

The proposed test protocol provides a basic sound scientific approach to the evaluation of the registrant's product. However, there are several specific details that require additional refinement listed above. These details above should be discussed with the Agency and worked out before the proposed method is used to generate sufficient data to demonstrate the product's effectiveness and reproducibility.