UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

October 29, 2001

MEMORANDUM:

Subject: Efficacy Review EPA Reg. 65402-3 Vigorox SP-15 Antimicrobial
DP Barcode 275882
Case No. 060170

From: Nancy Whyte, Microbiologist NWW
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Thru: Emily Mitchell, M.S., Team Leader Emily Mitchell 11/01/01
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Applicant: FMC Corporation
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Formulation Label:

Active Ingredient(s)	% by wt.
Peroxyacetic acid	15.0%
Inert Ingredients	85.0%
Total	100.0%

I. Background:

The registrant has submitted additional efficacy testing data (MRID No. 454158-01)

and a revised label for the purpose of changing label claims for the organism *Listeria monocytogenes* for which the product did not demonstrate effectiveness in the testing data submitted earlier this year. Submitted for review were the same data submitted previously, but the lab report was amended to include raw data to demonstrate that the product was effective at 100 ppm against Listeria, but not at 50 ppm. It does not appear that additional testing was undertaken, but that the raw data was added to the report first generated in 2000 and resubmitted with this amendment application.

II. Use Directions:

For use as a sanitizer for food contact surfaces and equipment such as beverage processing areas, dairies, meat, poultry and seafood processing plants, final sanitizing bottle rinses, eating establishments, and for sanitizing hatching eggs, the recommended dilution is 0.31 to 0.62 fluid ounces of product in 5 gallons of potable water. For use against *Listeria monocytogenes*, 0.4 to .61 ounces must be used. These dilutions provide 85 to 165 ppm of peroxyacetic acid. Equipment and bottles must be washed with soap or detergent after use and rinsed with potable water prior to treatment. The contact time for non-food contact equipment is one minute; for eating establishments it is at least 2 minutes. No contact time was given for eggs. All surfaces should be allowed to drain dry.

For use to sanitize tableware in low temperature warewashing machines a dilution of 0.5 to 0.62 ounces of the product in 5 gallons of potable water is required as a final rinse. For ambient temperatures (higher than 25°C) the dilution is 0.31 to 0.62 ounces in 5 gallons of potable water.

For packing house sanitization a dilution of 3.1 ounces in 50 gallons (85 ppm peroxyacetic acid) can be used as a coarse spray to reduce bacterial and fungal contamination of walls, floors, and harvesting containers. This same dilution is used on field equipment when equipment is placed on a impervious surface with controlled drainage. Care must be taken to ensure product is not released into the environment.

To treatment process water streams one fluid ounce in 16 gallons of water provides 85 ppm peroxyacetic acid. Contact time must be at least 45 seconds. The same dilution is used to treatment raw fruit and vegetable surfaces when the solution is used as either a spray or a soaking solution, but the contact time must be at least one minute. The directions on the label specify that "the treated produce can be drain dried without a potable water rinse".

III. Agency Standards for Proposed Change:

The Agency standards for food-contact sanitizers (sanitizing rinses) are found in DIS-TSS-4. Standards for non-food contact sanitizers are found in DIS-TSS-10. The organisms to be tested for non-food contact sanitizers are *Staphylococcus aureus,* ATCC 6538 and either *Klebsiella pneumoniae,* ATCC 4352 **or** *Enterobacter aerogenes,* ATCC 13048 or 15038. Microbial counts must be reduced by 99.999% within 30 seconds over the control for food-contact sanitizers, and reduced by 99.9% in 5 minutes for non-food contact sanitizers. Both standards require the use of three samples, representing 3 separate batches of the product, one at least 60 days old, to be tested for effectiveness.

IV. Summary of Submitted Study:

The efficacy testing to determine the effectiveness of the product as a sanitizer was conducted by Gibralter Laboratories, Inc. and was reported in three separate studies. The method used for testing was the *Official Methods of Analysis* of the Association of Official Analytical Chemists (AOAC), 16th ed., Chap 6-Disinfectants 960.09. The first testing (MRID No. 451823-01) was done in December 1999 and reported February 4, 2000. Two lots of the product, #40745 and #90909, (preparation dates not provided) were tested against *Escherichia coli,* ATCC 35150, *Salmonella typhimurium,* ATCC 14028 and *Listeria monocytogenes,* ATCC 984. The test product was diluted in 400 ppm AOAC hard water. Two diluents were prepared, one which had a final dilution of 50 ppm, the other 100 ppm. An organic soil load of 5% horse serum was added to the inoculum broths prior to introduction of the test organisms into the diluent in a suspension broth for a contact time of 30 seconds. After 30 seconds, the test solutions were diluted 10 fold and plated in quadruplicate, after which the plates were incubated for 48 hours at 37°C for 48 hours. The colonies were counted using a Quebec colony counter. In this study, the two lots of the products killed 99.999% of both *E. coli* and *Salmonella typhimurium* within 30 seconds at both 50 ppm and 100 ppm, demonstrating effectiveness of the product. **The same two lots of the product at 50 ppm did not kill 99.999% of *Listeria monocytogenes,* but did kill 99.999% of the same organism at 100 ppm**. The study did not suggest any explanation for this discrepancy. Log reductions of the product at both 50 ppm and 100 ppm against *E. coli* were $\geq$ 7.89. Against *Salmonella typhimurium,* the log reductions for both dilutions were $\geq$8.13. At 50 ppm the product reduced the count of *Listeria monocytogenes* by less than 5 logs, and at 100 ppm the log reduction for the same organism was $\geq$ 7.99.

The second study (MRID No. 451823-03) was conducted by the same laboratory, using the same procedures and following the same method, in December 1999 and January 2000. The organisms used this testing were *Escherichia coli,* ATCC 11229 and *Staphylococcus aureus,* ATCC 6538. Three samples of the product, one 60 days old, were used for this testing–Lot #15/10 received in July 1999 and Lot No. 90909 Batch #1 and Batch #2, received October 1999. Two exposure times, 30 seconds and 60 seconds, were used. No organic soil load was added to the inoculum prior to exposure to the product. At the registrant's request, the diluents of the product were prepared to give a final concentration of 75 ppm and 85 ppm, respectively. The dilutions were prepared in AOAC hard water.

The following results were obtained: All three lots of the product at both 75 ppm and 85 ppm reduced the number of *E. coli* for both contact times to $\geq$99.999%, demonstrating effectiveness of the product against this organism. None of the lots of the product at either 75 ppm or 85 ppm reduced the number of *Stapylococcus aureus* to the required number of 99.999% for either of the contact times. These results indicate that the product is not an effective sanitizer against *Staphylococcus aureus* for precleaned, nonporous food-contact surfaces.

In the third study (MRID No. 451823-02), the product was tested against *Staphylococcus aureus,* ATTC 6538. Three lots of the product, Lot #90624, #90909, and #91019, were used for contact times of 30 seconds and one minute. The testing was conducted in March 2000 by Gibralter Labs. No organic soil load was added to the inoculum and only a single dilution, 85 ppm, was used of each lot of the product for treatment. All lots demonstrated effectiveness at both contact times by reducing the number of organisms by

99.999% and indicating that the product is a effective sanitizer against *Staphylococcus aureus* for precleaned nonporous food-contact surfaces.

V. Labeling:

1. The revised draft copy of the label, Page 2 in the section "Sanitization of Non-porous Food Contact Surfaces" section, Item #5 states that "If sanitizing against *Listeria monocytogenes* use at least 0.4 ounces of product to 5 gallons of potable water" to prepare the working solution. This will **not** provide the minimum amount of peroxyacetic acid to achieve 100 ppm. At least 0.45 fluid ounces must be used to killing at the required rate of 99.999% reduction of organisms.

2. In the directions for use for field sanitization it is stated that equipment to be treated must be placed on "an impervious surface" and that the user "ensure that no sanitization solution will be released into the environment" The product is applied as a "general sanitizing coarse spray", and it is unreasonable to expect that no product will be released into the environment using any type of spray application. The use of an area with controlled drainage would also be difficult to obtain when treating field equipment. unless it was done inside a building with proper drainage and impervious floor surfaces.

VI. Comments and Recommendations:

1. The additional data from the initial efficacy data supports the use of a dilution of **0.45** (not 0.40%) fluid ounces of the product in 5 gallons of water to demonstrate effectiveness against *Listeria monocytogenes.* This direction for use (marked item #5 in both sections) must be lifted out of the general sanitization instructions and placed so that the user will notice that change from the directions given in item #4 in sections for Sanitization of Non porous Food-Contact Surfaces and Eating Establishment Sanitizing

2. No changes were made to the revised draft label directions for Field Equipment Sanitization, and the Agency comment made in V.2 above was not addressed. The registrant must provide the Agency with details which address the issue of containing a general coarse spray so that there is no release of product into the environment.

3. This resubmission completes the data required to support all label claims for effectiveness of the product against organisms which are listed.