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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 7, 2002

MEMORANDUM

Subject: Efficacy Review for EPA Reg. No. 65402-1 / VigorOx Liquid Sanitizer
and Disinfectant

DP Barcode: D280373

From: Ian Blackwell, Biologist
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Regulatory Management Branch I
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Applicant: FMC Corp

Formulation From Label:

Active Ingredient(s)
Peroxyacetic Acid
Hydrogen Peroxide
Inert Ingredient(s)
Total

	<u>% by wt</u>
	5.1
	21.7
	<u>73.2</u>
	100.00

- I **BACKGROUND:** FMC Corporation has submitted two product efficacy studies to support the registration of VigorOx Liquid Sanitizer and Disinfectant. The two studies were conducted by AppTec Laboratory Services. The MRID Numbers are 455540-01 and 455540-2.

The two studies submitted are food-contact surface sanitization studies. While VigorOx is already approved for the food-contact surface sanitization, these two studies were conducted using the company's foaming agent, VigorOx HRS in conjunction with VigorOx. The new submitted label has directions for "Sanitization Using Surfactants".

II Use Directions

VigorOx Liquid Sanitizer and Disinfectant is for Institutional/Industrial sanitizing of previously cleaned non-porous food contact surfaces such as:

- Eating, drinking and food preparation utensils
- Countertops, and food preparation surfaces
- Tableware
- Plastic, glass and metal bottles (rinse)

VigorOx Liquid Sanitizer and Disinfectant is for institutional sanitizing of previously cleaned non-porous food contact surfaces in:

- Dairies, wineries, breweries, and beverage plants
- Meat and poultry processing/packaging plants
- Milk and Dairy products processing/packing plants
- Seafood and produce processing packing plants
- Food processing/packing plants
- Egg processing/packing equipment surfaces
- Eating establishments

VigorOx Liquid Sanitizer and Disinfectant is for use in the disinfection of hard surfaces in general commercial and medical environments such as:

- Hospitals, health care facilities, veterinary hospitals/clinics, animal life science labs, pharmaceutical facilities and equipment
- Schools, colleges, recreational facilities, office buildings
- Livestock premises, poultry premises, poultry hatcheries, animals housing facilities
- Retail and wholesale establishments
- bathroom premises

III Agency Standards for Proposed Claims

Food Contact Surface Sanitizers: Efficacy of sanitizing rinses formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, and anionic detergent-acid formulations must be substantiated with data derived from the AOAC Germicidal and Detergent Sanitizers Method.

- 1 Test requirements. Data from the test on one sample from each of 3 different batches, one of which is at least 60 days old, against both *E. coli* and *S. aureus* are required. When claims for the effectiveness of the product in hard water are made, all required data must be developed at the hard water tolerance claimed.
- 2 Performance standard. 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 percentage reduction over the control. The minimum concentration of the product which provides the results required above is the minimum effective concentration.

IV Comments on the Submitted Efficacy Studies

- 1 45540-01: "Germicidal and Detergent Sanitizing Action of Disinfectants" by Marc S. Finley. AppTec Laboratory Services. Project Number 11991. Study Completion Date 11/21/2001.

This study was conducted to assess the ability of EPA Registration Number 65402-1 to act as a food contact surface sanitizer. The study was using the two test organisms *Staphylococcus aureus* (ATCC 6538) and *Escherichia coli* (ATCC 11229). The product label states that the registration product may be prepared by diluting in water, or, by diluting in VigorOx HRS for sanitizing non-porous food-contact surfaces. The diluent solution for VigorOx was prepared by adding 8.341 g of KF-G1616-624MGC to a flask of 200 g (mL) of sterile deionized water. An amount of 0.844 g of VigorOx was added to the mixture. A volume of 290.82 mL of filtered water was added to that mixture, bringing the total volume up to 500 mL. 99 mL of each lot of germicide was added to 9 each of two 250 mL wide mouth Erlenmeyer flasks and placed into a 25°C water bath for at least 20 minutes. One mL of culture suspension was added to each flask. After a 30 or 60 second exposure, one mL of exposed culture/disinfectant mixture was added from each flask to 9 mL Lethen broth with 0.5% Sodium Thiosulfate to neutralize the sanitizer. After mixing, four 1.0 mL and four 0.1 mL aliquots were transferred from each tube to individual sterile petri dishes. Fifteen to 20 mL of tryptone glucose extract agar was added to each plate. The agar plates were

cooled to solidify, inverted and incubated for 48 hours at 35°C before performing a bacteria count.

- 2 MRID Number 455540-02: "Germicidal and Detergent Sanitizing Action of Disinfectants" by Marc S. Finley. AppTec Laboratory Services. Project Number 11990. Study Completion Date 11/28/2001.

This study was also conducted to determine the ability of VigorOx Citrus XA (EPA Registration Number 65402-6) to sanitize hard, non-porous, food contact surfaces. This study was conducted using *Staphylococcus aureus* and *Escherichia coli*. The diluent solution for VigorOx Citrus XA was prepared by adding 8.34 g of KF-G1616-62-4MGC to a flask of 200 g (mL) of sterile deionized water. An amount of 0.84 g of VigorOx Citrus XA was added to the mixture. A volume of 290.82 mL of filtered water was added to that mixture, bringing the total volume up to 500 mL. 99 mL of each lot of germicide was added to 9 each of two 250 mL wide mouth Erlenmeyer flasks and placed into a 25°C water bath for at least 20 minutes. One mL of culture suspension was added to each flask. After a 30 or 60 second exposure, one mL of exposed culture/disinfectant mixture was added from each flask to 9 mL Letheen broth with 0.5% Sodium Thiosulfate to neutralize the sanitizer. After mixing, four 1.0 mL and four 0.1 mL aliquots were transferred from each tube to individual sterile petri dishes. Fifteen to 20 mL of tryptone glucose extract agar was added to each plate. The agar plates were cooled to solidify, inverted and incubated for 48 hours at 35-37°C before performing a bacteria count.

V Results

Table 1 From MRID Number 455540-01

<i>Escherichia coli</i>				
Test Substance	Exposure Time	Average Number Surviving	Microbes Initially Present	Percent Reduction
VigorOx Batch #0000363524	30 sec.	<1	7.9 x 10 ⁷	> 99.999
	60 sec.	<1		>99.999
Vigor Ox Batch #0000420218	30 sec.	<1		>99.999
	60 sec.	<1		>99.999

Table 2 From MRID Number 455540-01

<i>Staphylococcus aureus</i>				
Test Substance	Exposure Time	Average Number Surviving	Microbes Initially Present	Percent Reduction
VigorOx Batch #0000363524	30 sec.	<1	7.5 x 10 ⁷	>99.999
	60 sec.	<1		>99.999
Vigor Ox Batch #0000420218	30 sec.	<1		>99.999
	60 sec.	<1		>99.999

Table 3 From MRID Number 455540-02:

<i>Staphylococcus aureus</i>				
Test Substance	Exposure Time	Average Number Surviving	Microbes Initially Present	Percent Reduction
VigorOx Batch #0000349323	30 sec.	<1	7.5 x 10 ⁷	> 99.999
	60 sec.	<1		>99.999
Vigor Ox Batch #0000419855	30 sec.	<1		>99.999
	60 sec.	<1		>99.999

Table 4 From MRID Number 455540-02:

<i>Escherichia coli</i>				
Test Substance	Exposure Time	Average Number Surviving	Microbes Initially Present	Percent Reduction
VigorOx Batch #0000349323	30 sec.	<1	7.9 x 10 ⁷	> 99.999
	60 sec.	<1		>99.999
Vigor Ox Batch #0000419855	30 sec.	<1		>99.999
	60 sec.	<1		>99.999

INERT INGREDIENT INFORMATION IS NOT INCLUDED

VI Conclusions

- 1 The submitted efficacy data (MRID Numbers 455540-01) appears to support the use of the product, VigorOx, as a sanitizer with activity when tested against *Staphylococcus aureus* and *Escherichia coli* with contact times of 30 and 60 seconds at room temperature (25 °C). However, there is one problem with the study: the label states that VigorOx can be diluted from 1.0-1.7 ounces per 5 gallons for sanitization. However, the study did not test the most dilute concentration listed, 1.0 ounce per 5 gallons, but tested 1.12 ounces per 5 gallons.
- 2 This study (MRID Number 455540-02) was actually conducted on EPA Registration Number 65402-6. VigorOx Citrus XA is actually the same product as VigorOx without [REDACTED]. This study supports the use of 65402-6 as a food contact surface sanitizer.

VII Recommendations

1. The request to add label claims of VigorOx being a food contact-surface sanitizer is acceptable.
2. The request to add label claims of VigorOx Citrus XA being a food contact-surface sanitizer is acceptable.
3. The label states that VigorOx can be used at concentrations as dilute as 1.0 ounces per 5 gallons of VigorOx HRS for sanitization. However, the data submitted only substantiate concentrations of 1.12 ounces per 5 gallons or stronger (more concentrated). This label statement must be changed to state that the product may be used at dilutions of 1.12 ounces per 5 gallons until substantiating data has been submitted.

The product label states that the product may be prepared using 1 to 10 ounces per 5 gallons of VigorOx HRS. While the product may be used effectively at a concentration of 1.12 ounces per 5 gallons, and 10 ounces per 5 gallons, it is not necessary to use as much as 10 ounces per 5 gallons.

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4. The product label has new directions for mixing the 65402-1 into sodium lauryl sulfate instead of water or VigorOx HRS foam. Currently, however, no data have been submitted to substantiate these alternate mixing directions. Therefore, remove the directions for use with sodium lauryl sulfate, or, submit data to substantiate this claim.