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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 25, 2002

MEMORANDUM:

Subject: Efficacy Review for EPA Reg. No.: 74286-R "Dishwasher Magic®"
DP Barcode: D280547
Case No: 071137

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

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

To: Adam Heyward, PM 34
Regulatory Management Branch II
Antimicrobials Division (7510C)

Applicant: Wagner Regulatory Associates, Inc.
P.O. Box 7954
Wilmington, DE 19803-0954

Formulation From Label:

Active Ingredient(s)	% by wt.
Citric Acid	25.0%
Inert Ingredient(s)	75.0%
Total	100.0%

I BACKGROUND:

Wagner Regulatory Associates, Inc. submitted efficacy data for their product "Dishwasher Magic®", EPA Registration No., 74286-R. The data package was received by the Agency 08-01, which contained a letter from the company and two efficacy studies, MRID Nos. 454814-01 & 454814-02.

II USE DIRECTIONS:

The product, "Dishwasher Magic®" is intended for use in automatic dishwashers to remove lime scale, soap scum, calcium, grease, iron and staining. Also, the product claims to kill 99.9% of *Salmonella choleraesuis*, and *Escherichia coli* on the interior surfaces of the dishwasher. Make sure your automatic dishwasher is empty. Place the bottle upside down in the bottom rack inside the silverware basket. Do not use soap. Close dishwasher door, then set to normal wash cycle. Start dishwasher. After full cycle is complete, and dishwasher is off, remove bottle and discard. When the waters inside the dishwasher reaches 125°F (in wash cycle), the red plug in the bottle will dissolve and the solution inside will dispense.

III AGENCY STANDARDS FOR PROPOSED CLAIMS:

The Agency standards for supplementary label claims for effectiveness of the product against public health organisms is found in DIS-TSS-1 and DIS-TSS-2 which specifies the use of the methods outlined in the Association of Official Analytical Chemists (AOAC) Use-Dilution Method for products. Sixty carriers must be tested against each of both *Salmonella choleraesuis* and *Staphylococcus aureus* with each of 3 samples, representing 3 different batches, one of which is at least 60 days old. Killing 59 out of each set of 60 carriers is required to provide effectiveness at the 95% confidence level. The Agency standards for sanitizing label claims for effectiveness of the product against public health organisms is found in DIS-TSS-4 and DIS-TSS-10 which specifies the use of the methods outlined in the Association of Official Analytical Chemists (AOAC) Germicidal and Detergent Sanitizing Action of Disinfectants. DIS- TSS-4 may be used to test for food contact surface sanitizers. Efficacy for sanitizing rinses formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, and anionic detergent-acid formulations must be substantiated with data from one sample from each of 3 different batches, one of which is at least 60 days old, against *Escherichia coli* and *Staphylococcus aureus*. 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. DIS-TSS-10 may be used to test for non-food contact surface sanitizers. Three product samples, representing 3 different preparations, one of which is at least 60 days old, should be tested against each test bacterium on each test surface. The test bacteria are *Staphylococcus aureus* and *Klebsiella pneumoniae*. *Enterobacter aerogenes* may be substituted for *Klebsiella pneumoniae*. The test surface(s) represent the types of surfaces recommended for

treatment on the label including, but not limited to glass, metal, unglazed or glazed ceramic tile, porcelain, or vitreous china. The results of the testing must demonstrate a bacterial reduction of at least 99.9% over the parallel control count within 5 minutes.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES:

Data Summary:

MRID No. 454814-01 - The efficacy study was conducted by Donna B. Suchmann, MicroBioTest Inc., 105B Carpenter Drive, Sterling, VA 20164, dated June 26, 2001.

The test method used was the A. O. A. C. Use-Dilution Method, 15th Edition, 1990 and EPA's Pesticide Assessment Guidelines Subdivision G: Product Performance Section: 91-2(b). The product, (Lot Nos. 3-12012-1, 9-12012-0, and 12-12012-0) was tested against *Salmonella choleraesuis* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538) for 12 minutes at 51±1°C.

Salmonella choleraesuis 7.2×10^5
Staphylococcus aureus 6.4×10^6

MRID No. 454814-02 - The efficacy study was conducted by Donna B. Suchmann, MicroBioTest Inc., 105B Carpenter Drive, Sterling, VA 20164, dated July 19, 2001.

The test method used was the A. O. A. C. Use-Dilution Method, 15th Edition, 1990 and EPA's Pesticide Assessment Guidelines Subdivision G: Product Performance Section: 91-2(b). The product, (Lot Nos. 3-12012-1 and 12-12012-0) was tested against *Escherichia coli* (ATCC 11229) for 12 minutes at 51±1°C.

Escherichia coli 7.8×10^5

V RESULTS:

MRID No. 454814-01

Lot No.	Microorganism	No. Positive/ Total No.
3-12012-1	*Salmonella choleraesuis*	0/60
	Staphylococcus aureus	9/60
9-12012-0	*Salmonella choleraesuis*	0/60
	Staphylococcus aureus	22/60
12-12012-0	*Salmonella choleraesuis*	0/60

	Staphylococcus aureus	32/60

MRID No. 454814-02

Escherichia coli

Lot No.	No. Positive/Total No.
3-12012-2	0/10
12-12012-0	0/10

VI CONCLUSIONS:

When tested at a dilution of 12 fluid ounces of the product to 7 quarts of water (400 ppm hard water) at 51±1°C for an exposure time of 12 minutes, Dishwasher Magic was effective against the test organisms, *Salmonella choleraesuis* (ATCC 10708) and *Escherichia coli* (ATCC 11229). When tested at a dilution of 12 fluid ounces of the product to 7 quarts of water (400 ppm hard water) at 51±1°C for an exposure time of 12 minutes, Dishwasher Magic **was not effective** against the test organism, *Staphylococcus aureus* (ATCC 6538).

If the product is to be registered as a hard surface disinfectant, then the product must meet EPA guidelines for general disinfection claims. Sixty carriers must be tested against each of both *Salmonella choleraesuis* and *Staphylococcus aureus* with each of 3 samples, representing 3 different batches, one of which is at least 60 days old. Killing 59 out of each set of 60 carriers is required to provide effectiveness at the 95% confidence level.

If the product is to be registered as a food contact surface sanitizer, efficacy for sanitizing rinses formulated with quaternary ammonium compounds, chlorinated trisodium phosphate, and anionic detergent-acid formulations must be substantiated with data from one sample from each of 3 different batches, one of which is at least 60 days old, against *Escherichia coli* and *Staphylococcus aureus*. 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.

If the product is to be registered as a non-food contact surface sanitizer, efficacy for three product samples, representing 3 different preparations, one of which is at least 60 days old, should be tested against each test bacterium on each test surface. The test bacteria are *Staphylococcus aureus* and *Klebsiella pneumoniae*. *Enterobacter aerogenes* may be substituted for *Klebsiella pneumoniae*. The test surface(s) represent the types of surfaces recommended for treatment on the label including, but not limited to glass, metal, unglazed or glazed ceramic tile, porcelain, or vitreous china. The results of the testing must demonstrate a bacterial reduction of at least 99.9% over the parallel control count within 5 minutes.

In either case, the registrant must submit additional efficacy data to support this product. If the registrant chooses to label the product as a non-food contact surface sanitizer, a control should be incorporated into the procedure. The control would be the 51±1°C water. The product tested at this temperature should meet at least a 3 log

reduction over the control.

Also, the product should be tested under "worst case" scenario, regardless of the label claims. The registrant stated, the product was tested at 125°F for "worst case" conditions. However, this would not be "worst case" because the 125°F water temperature was used to melt the plug in the bottle to release the contents of the product.

VII LABELING COMMENTS:

A full label review cannot be completed until the above data requirements have been satisfied.