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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Edmar Chemical Company P.O. Box 598 Chagrin Falls, OH 44022 APR 17 2000

Subject: Bio-Magic Rinse Powder EPA Registration No. 7048-2 Amendment Date: 12/23/99 EPA Receive Date: 12/30/99

Attention: Mr. Jack Binder

The amendment referenced above, submitted in connection with registration under FIFRA, as amended, to update product label is acceptable provided you address the following comments before you release this product for shipment.

The claim, "renders treated fabric bacteriostatic against S. aureus and antibiotic resistant strains of Streptococcus pyogenes", is unacceptable because "Bacteriostat" is a nonpublic health claim typically associated with inhibiting the growth of odor causing bacteria and mold/mildew. S. aureus and antibiotic resistant strains of Streptococcus pyogenes are public health organisms that are associated with infectious diseases. "The Agency requires that products bearing label claims of effectiveness against specific infectious microorganisms must eliminate those microorganisms, or significantly reduce their numbers, and NOT merely inhibit their growth. Mere growth inhibition (bacteriostatis) cannot be considered where_ microorganisms of public health concerns are involved" (See Attachment). You will need to delete the organisms, S. aureus and antibiotic resistant strains of Streptococcus pyogenes from the label until you provide efficacy data showing this product's effectiveness as a laundry additive sanitizer and/or disinfectant against them.

Also, you should note that the claim, "Provides continuous ANTIBACTERIAL activity on treated fabric." will also need to be either supported by efficacy data when you amend your label adding public health organisms or deleted. The Agency suggests that you contact us regarding the appropriate efficacy data protocol for this type of claim.

The Agency is unclear in regard to the submitted primary skin irritation study. The study represents a product's concentration diluted to 9.144%. What formulation is being diluted? Is

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the formulation identical or substantially similar to Bio-Magic Rinse and/or Bio-Magic Rinse Powder? Bio-Magic Rinse contains 12.0% active ingredient. How does the submitted study represent this product's primary skin toxicity? If you would like to revise your primary skin irritation toxicity category to IV, you will need to submit primary skin irritation data on the specific product's formulation. Until the Agency receives such data, the primary skin irritation toxicity category for this product will remain Category I.

A stamped label is enclosed for your records. Please submit a final printed label to the Agency before you release this product for shipment. If you have any questions regarding this letter, please contact Jacqueline Campbell at (703) 308-6416.

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Sincerely.

Velma Noble Product Manager 31 Regulatory Management Branch I Antimicrobials Division (7510C)

 Enclosure:
 DIS/TSS 13
 Efficacy Data and Labeling Requirements for Laundry Additives-Disinfection and Sanitization

 Excerpt
 Subdivision H:Labeling Guidance for Antimicrobial Pesticide Products

 p. 3



Provides continuous <u>ANTIBACTERIAL</u> activity on treated fabric.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Use 1.5 ozs. per 100 lbs. of fabric, dry weight, in the final warm rinse cycle, at a low water level. Run for a minimum of 8 minutes. DO NOT USE IN THE PRESENCE OF OTHER CHEMICALS OR PREMIX WITH OTHER CHEMICALS.

BIO-MAGIC RINSE™ is a special treatment to be used as an adjunct to standard laundering routine. It is not intended as a terminal disinfectant for fabric or hard surfaces.

WHEN USED AS DIRECTED

BIO-MAGIC RINSE™ renders treated fabric bacteriostatic against Staphylococcus aureus; arrests the growth of antibiotic resistant strains of Streptococcus pyogenes.

BIO-MAGIC RINSE[™] softens fabrics, provides production benefits in various stages of laundering, and extends fabric life by lubricating fibers.

FIRST AID

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store in original container. Keep from freezing. Keep away from heat or flame. **Pesticide Disposal:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate, is a violation of Federal law. If these wastes cannot be disposed of by use, according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated, dispose of in the same manner.

ENVIRONMENTAL HAZARDS

This product is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, tact your State Water Board or Regional Office of the EPA.

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