

7048-4

04/17/2000

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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
EPA Registration No. 7048-4
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.

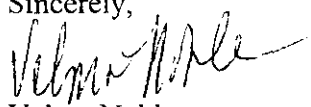
The claim, "fabric bacteriostat against *S. aureus*, *K. pneumonia*, and *B. ammoniagenes*", is unacceptable because "Bacteriostat" is a non-public health claim typically associated with inhibiting the growth of odor causing bacteria and mold/mildew. *S. aureus*, *K. pneumonia*, and *B. ammoniagenes* 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*, *K. pneumonia*, and *B. ammoniagenes* from the label until you provide efficacy data showing this product's effectiveness as a laundry additive sanitizer and/or disinfectant against them.

The Agency is unclear in regard to the submitted primary skin irritation study. The study represents a product's concentration diluted to 0.144%. What formulation is being diluted? Is 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.

CONCURRENCES

SYMBOL	75100							
SURNAME	Cambridge							
DATE	4/17/00							

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.

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

Subdivision H: Labeling Guidelines for Pesticide Use Directions for
Antimicrobial Products p. 3

BIO-MAGIC RINSE™

Concentrated Liquid Softener-Bacteriostat

EPA. REG. NO. 7048-4 • EPA. EST. NO. 36522-011-01-

ACTIVE INGREDIENT: n-Alkyl (60% C₁₄, 30% C₁₆, 5% C₁₂, 5% C₁₈) Dimethyl benzyl ammonium chloride 6.0%
n-Alkyl (50% C₁₂, 30% C₁₄, 17% C₁₆, 3% C₁₈) Dimethyl ethylbenzyl ammonium chloride 5.0%
OTHER INGREDIENTS: 88.0%
TOTAL: 100.0%

Keep Out of Reach of Children - DANGER

ACCEPTED
with COMMENTS
in EPA Letter Dated:
APR 17 2000

EDMAR CHEMICAL COMPANY

CLEVELAND, OHIO • 1-800-678-7018

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 7048-4

Precautionary Statements
Hazards To Humans & Domestic Animals.
KEEP OUT OF REACH OF CHILDREN

DANGER

Corrosive. Causes irreversible damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear (goggles or face shield), rubber gloves and protective clothing. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

For Commercial & Institutional use only.

LOT #: 8124

55 GAL.

DIRECTIONS FOR USE

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

Use 2.5 ozs. per 100 lbs. of fabric, dry weight, in the final, warm rinse cycle at a low water level. Dilute the appropriate amount of BIO-MAGIC RINSE™ in 1 gallon of water; then add to the wash in the final rinse, or dispense directly through automatic dispensing equipment. Run for a minimum of 8 minutes. Retreat as necessary. **DO NOT USE IN THE PRESENCE OF OTHER CHEMICALS OR PRE-MIX WITH OTHER CHEMICALS!**

BIO-MAGIC RINSE™ is 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, Klebsiella pneumoniae, B. ammoniagenes, under conditions of high humidity and wet contamination.

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: Triple rinse container (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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, contact your State Water Board or Regional Office of the EPA.

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