

421-435

05-21-2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 21 2004

Mr. Chester J. Sempkowski
Technical Director
James Varley & Sons, LLC
1200 Switzer Ave
St. Louis, MO 63147

Subject: **Mist-Away Cleaner Disinfectant**
EPA Registration Number 421-435
Application Dated February 17, 2004
EPA Received Date February 23, 2004

Dear Mr. Sempkowski:

The following amendment, submitted in connection with registration the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comments:

Proposed Amendment:

- revise labeling per EPA letter 12/2/03

General Comments:

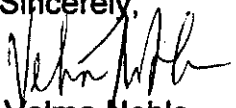
A stamped copy of the labeling accepted with conditions is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Should you have any questions or comments concerning this letter, please contact Drusilla Copeland on (703) 308-6224.

Sincerely,



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

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
KEEP OUT OF REACH OF CHILDREN
CAUTION**

Causes moderate eye irritation. Avoid contact with eyes or skin and clothing. Harmful if inhaled or absorbed through skin. Avoid breathing vapor or spray mist. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS: 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 Pollutant 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.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice. **If on skin:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. **If inhaled:** Move person to fresh air. If person is not breathing call 911 or ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice. **If swallowed:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

PESTICIDE STORAGE: Keep product under locked storage, inaccessible to children.

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—Metal Containers:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in sanitary landfill, or by other procedures approved by state and local authorities. **Plastic Containers:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in sanitary landfill or incineration, or if allowed by state and local authorities, by burning, if burned, stay out of smoke. **FOR 1 GALLON OR LESS:** Do not reuse empty container (bottle, can, bucket). Wrap (container) and put in trash.

DIRECTIONS FOR USE

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

This product is not for use on medical device surfaces.

This cleaner-disinfectant is a proven "one step" disinfectant-cleaner-sanitizer-fungicide-mildewstat-virucide which is effective in water up to 400 ppm hardness in the presence of 5% serum contamination. Apply this cleaner-disinfectant undiluted. For heavily soiled areas, a preliminary cleaning is required. Use a fresh solution daily or when use solution becomes visibly dirty.

Disinfectants: To disinfect hard, non-porous surfaces, treated surfaces must remain wet for 10 minutes. This cleaner-disinfectant is also virucidal and fungistatic. **For Schools, Industry & Medical Institutions Use:** The broad spectrum activity of this cleaner-disinfectant has been evaluated and found to be effective against the following organisms by the A.O.A.C. Use-Dilution Test: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli*, *Streptococcus pyogenes*, *Salmonella choleraesuis*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Streptococcus faecalis*, *Shigella dysenteriae*, *Salmonella typhi*, *Brevibacterium ammoniagenes*, *Serratia marcescens*.

HAZARD RATING: 1 - Health, 0 - Fire, 0 - Reactivity, 0 - Special



VARLEY

**Mist Away
Cleaner • Disinfectant**

**DISINFECTANT-CLEANER-SANITIZER-FUNGICIDE
MILDWSTAT-VIRUCIDE* -DEODORIZER FOR HOSPITALS**

ACTIVE INGREDIENTS:

Octyl decyl dimethyl ammonium chloride	0.0280%
Dioctyl dimethyl ammonium chloride	0.0104%
Didecyl dimethyl ammonium chloride	0.0158%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₈ , 10%) dimethyl benzyl ammonium chloride	0.0340%
INERT INGREDIENTS	99.9140%
TOTAL	100.0000%

EPA Reg No. 421-435 EPA Est. No. 421-MB-01

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See left panel for additional precautionary statements.

NET CONTENTS - GALLON(s): 1 5 55

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 21 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 421-435

A.O.A.C. Fungicidal Test: This cleaner-disinfectant is effective against mold and mildew on hard porous and non-porous surfaces. **Mold & Mildew Control:** This cleaner-disinfectant is an effective sanitizer on hard porous and non-porous, environmental spray so as to thoroughly wet surfaces. To clean and/or deodorize: Apply to surfaces. Wipe dry with a clean cloth or sponge.

Sanitizing Non-Food Contact Surfaces: This cleaner-disinfectant is an effective sanitizer on hard porous and non-porous, environmental spray so as to thoroughly wet surfaces. To clean and/or deodorize: Apply to surfaces. Wipe dry with a clean cloth or sponge.

Virucidal Performance: This cleaner-disinfectant is an effective sanitizer on hard, non-porous, inanimate environmental surfaces. ***KILLS HIV ON PRE-CLEANED, SOILED SURFACES/OBJECTS SOILED WITH BLOOD/BODILY FLUIDS:** An expected likelihood of soiling of inanimate surfaces/objects likely to be soiled with transmission of human immunodeficiency virus (HIV).

***SPECIAL INSTRUCTIONS FOR USE ON SURFACES/OBJECTS SOILED WITH BLOOD/BODILY FLUIDS:** Leave surface wet for 10 minutes. **CLEANING PROCEDURE:** Blood and other fluids should be removed from surfaces/objects before application.

PERSONAL PROTECTION: Clean gowns, masks and eye protection. **DISPOSAL OF INFECTIOUS MATERIALS:** should be autoclaved and disposed of as hazardous waste.

A quality product
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