

421-434

05-18-2004

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 18 2004

Mr. Chester J. Sempkowski
Technical Director
J. F. Daley International Ltd.
Peck's Products Division
1200 Switzer Ave.
St. Louis, MO 63147

Subject: **#25 Quaternary Ammonium Cleaner Disinfectant**
EPA Registration Number 421-434
Application Dated March 11, 2004
EPA Received Date March 30, 2004

Dear Mr. Sempkowski:

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

Proposed Amendment:

- revise labeling per EPA letter 12/19/03

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)

Enclosure

Precautionary Statements - Hazards to Humans & Domestic Animals

DANGER: KEEP OUT OF REACH OF CHILDREN: Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing, and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, or using tobacco. Remove contaminated clothing and wash 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 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. **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.
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.
PESTICIDE STORAGE: Keep container closed when not in use in an area inaccessible to persons unfamiliar with its use. Do not store below 32°F or above 100°F.
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 OR PLASTIC CONTAINERS:** Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. 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.

Cross-contamination is of major concern not only in hospitals, but in schools, institutions and industry. This quaternary ammonium cleaner-disinfectant is formulated for this problem area. It both cleans and disinfects effectively and is virucidal when used as directed. Its hard surface disinfecting action will reduce the hazard of cross-contamination from environmental surfaces.

When used as directed, this quaternary ammonium cleaner-disinfectant will deodorize toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas and will inhibit the growth of mold and mildew and their odors when used as directed. This product is economical to use because it is highly concentrated and should be handled with care.

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 quaternary ammonium cleaner-disinfectant is a proven "one-step" cleaner-disinfectant-sanitizer-fungicide-virucide in the presence of moderate amounts of organic soil. Apply this quaternary ammonium cleaner-disinfectant to walls, floors and other hard (inanimate), non-porous surfaces such as tables, chairs, counter-tops and sinks with a cloth, mop or coarse spray so as to thoroughly wet surfaces. For heavily soiled areas, a preliminary cleaning is required. Prepare a fresh solution daily or when use solution becomes visibly dirty.



VARLEY

#25 QUATERNARY AMMONIUM CLEANER-DISINFECTANT

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

ACTIVE INGREDIENTS:	
Octyl decyl dimethyl ammonium chloride	3.750%
Dioctyl dimethyl ammonium chloride	1.500%
Didecyl dimethyl ammonium chloride	2.250%
Alkyl (C ₁₄ , 50%; C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride	5.000%
INERT INGREDIENTS	87.500%
TOTAL	100.000%

EPA Reg No. 421-434 EPA Est. No. 421-M8-01

KEEP OUT OF REACH OF CHILDREN
DANGER

See left panel for additional precautionary statements.

NET CONTENTS - GALLON(S): 1 5 55

Disinfection: To disinfect hard, non-porous surfaces, wet with solution. Allow surfaces to remain wet for 10 minutes. At this use-level, this Wipe surfaces dry with cloth, mop, sponge, or brush with potable water. Do not use on dishes, glass, or plastic. **Sanitizing:** To sanitize porous or non-porous surfaces, wet with solution. Allow surfaces to remain wet for 30 seconds. **1/2 oz. per gallon use-level:** The broad spectrum activity of this product is evaluated in the presence of 5% serum and found to be effective against: **Pseudomonas aeruginosa • Staphylococcus aureus • Klebsiella pneumoniae • Enterobacteriaceae • Streptococcus**

A.O.A.C. Fungicidal Test: This quaternary ammonium cleaner-disinfectant is effective against dermatophytes (the athlete's foot fungus) when used on exercise areas, dressing rooms.
Mildewstatic Performance: At 1/2 oz. per gallon use-level, it inhibits the growth of mold and mildew and is indicated in general instructions above. Allow to remain wet for 10 minutes.
***Virucidal Performance:** At 1/2 oz. per gallon use-level, it is effective against the presence of 10% serum and found to be effective against the virus family that causes infectious mononucleosis (the Hong Kong flu virus) and HIV-1. **Sanitizing Non-Food Contact Surfaces:** At 1/2 oz. per gallon use-level, 30 second contact time, this quaternary ammonium cleaner-disinfectant is effective against up to 600 ppm hardness against Staphylococcus aureus on porous and non-porous environmental surfaces. ***KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES WITH BLOOD/BODY FLUIDS** in health care settings. ***KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES WITH BLOOD/BODY FLUIDS** in health care settings. ***SPECIAL INSTRUCTIONS FOR CLEANING SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:** Leave surface wet for 10 minutes. **CLEANING PROCEDURE:** Blood and other body fluids can be associated with the potential for HIV. **PERSONAL PROTECTION:** Clean up thoroughly. **DISPOSAL OF INFECTIOUS MATERIALS:** Autoclaved and disposed of according to local regulations.

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