

421-434

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DEC 19 2003

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

Subject: #25 Quaternary Ammonium Cleaner-Disinfectant
EPA Registration No. 421-434
Amendment Date: September 11, 2003
EPA Receipt Date: September 22, 2003

Dear Mr. Sempkowski,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with the following conditions .

- Update First Aid Statements per PR Notice 2001-1

Conditions

Revise the label as follows:

1. Under the Ingredients Statement, Add "Total 100%."
2. Revise the "Precautionary Statement" to state *"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, faceshield, 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."*
3. Under the disinfecting directions, add the statements, *"Wipe surfaces dry with cloth, mop, sponge, or allow to air dry. Rinse food contact surfaces such as counters, tables, stovetops with potable water. Do not use on dishes, glasses, utensils, or cookware."*
4. Revise the Sanitizing directions to state "Apply 1/4 oz per gallon of water. Treated surfaces must remain wet for 30 seconds. Allow surfaces to air dry or remove excess liquid with cloth, mop, or sponge."

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5. The Agency has asked registrants to begin submitting "Master" labels which contain all the claims, use sites, directions, storage/disposal statements, and environmental hazard statements on one label. Based on the "Application for Pesticide," this product is sold in containers ranging from 32 oz to 55 gallon drums. You should revise your label to bring it into compliance with the above criteria for a "master label by addressing the following comments:

A) Revise the Storage and Disposal section as follows:

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° or above 100°F.

Pesticide Disposal: Statements are acceptable.

Container Disposal: Statements are correct.

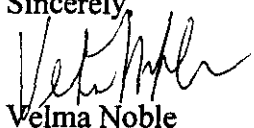
B) You should note that only containers greater than 5 gallons are required to carry the Environmental Hazard statements.

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

If you have any questions regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



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

Enclosure: Stamped Label		CONCURRENCES						
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Precautionary Statements - Hazards to Humans & Domestic Animals

DANGER: KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes severe eye and skin damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. Avoid contamination of food.

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. Open dumping is prohibited. Do not reuse empty container.

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 ₁₈ , 10%) dimethyl benzyl ammonium chloride	5.000%
INERT INGREDIENTS	87.500%

EPA Reg No. 421-434

EPA Est. No. 421-MB-81

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See left panel for additional precautionary statements.

NET CONTENTS - GALLON(S): ☐ 1 ☐ 5 ☐ 55

Disinfectant: To disinfect hard, main wet for 10 minutes. At this use-level. **Sanitizing:** To sanitize porous 1/2 oz. per gallon use-level. The evaluated in the presence of 5% soil.

Pseudomonas aeruginosa • **Enterobacteriaceae** • **Staphylococcus aureus** • **Streptococcus**

A.O.A.C. Fungicidal Test: The **Trichophyton** (the white's foot fungus) source area, dressing room.

Mildewstat: Performance: At inhibit the growth of mold and mildew indicated in general instructions above.

***Virucidal Performance:** At 1/2 presence of 10% serum and found to be of the virus family that causes influenza A2 (the Hong Kong flu virus).

Sanitizing Non-Food Contact use-level: 30 second contact time, waters of up to 600 ppm hardness against porous and non-porous environments.

***KILLS HIV ON PRE-CLEAN WITH BLOODBODY FLUIDS** acting of inanimate surface objects or body fluids can be associated with AIDS.

***SPECIAL INSTRUCTIONS SURFACES/OBJECTS SOILED** CONTACT TIME: Leave surface wet.

CLEANING PROCEDURES: Bloods before application of this product.

PERSONAL PROTECTION: No protection.

DISPOSAL OF INFECTION: autoclaved and disposed of according

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