

James Varley & Sons, Inc.
 1200 Switzer Avenue
 St. Louis, MO 63147

JAN 16 1998

Dear Mr. Chester J. Sempkowski:

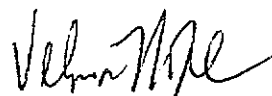
Subject: #25 Quaternary Ammonium Cleaner/Disinfectant
 EPA Registration No. 421-434
 Your Submission Dated October 14, 1997
 EPA Received Date of October 18, 1997

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. The basic label is acceptable at the proposed concentration of one-half ounce of product per gallon of water. "Anti-Staph 64" is acceptable for the alternate brand name at the use rate of two ounces of product per gallon of water. "Anti-Staph 32" is acceptable for another alternate brand name at the use rate of four ounces of product per gallon of water. All three labels have been placed in the product file.

A stamped copy of the basic label is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Julie Fairfax at (703) 308-9086.

Sincerely yours,



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

Enclosure

7510W:J.Fairfax:1/15/98:421-434				CONCURRENCES			
SYMBOL	7510W						
SURNAME	J.Fairfax						
DATE	1/16/98						

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.

STATEMENT OF PRACTICAL TREATMENT: In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse. If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately. **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. **STORAGE:** Keep container closed when not in use. **PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. **CONTAINER DISPOSAL:** Metal Containers. Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a 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 a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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 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 (non-porous), non-porous surfaces such as tables, chairs, countertops, sinks and bedframes 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.

Disinfection: To disinfect hard, non-porous surfaces: Add 1/2 oz. per gallon of water. Treated surfaces must remain wet for 10 minutes. At this use-level, this quaternary ammonium cleaner-disinfectant is also virucidal and fungicidal.



25 QUATERNARY AMMONIUM CLEANER - DISINFECTANT

Disinfectant - Cleaner - Sanitizer - Fungicide
Mildewstat - Virucide* - Deodorizer for Hospitals

INSTITUTIONAL & INDUSTRIAL USE

ACTIVE INGREDIENTS:

Octyl decyl dimethyl ammonium chloride	3.750%
Dioctyl dimethyl ammonium chloride	1.500%
Didecyl dimethyl ammonium chloride	2.250%
n-Alkyl (C ₁₄ 50%; C ₁₂ 40%; C ₁₆ 10%) dimethyl benzyl ammonium chloride	5.000%
INERT INGREDIENTS	87.500%

EPA Reg. No. 421-434

EPA Est. No. 421-MO-01

**KEEP OUT OF REACH OF CHILDREN
DANGER**

(See side panel for additional precautionary statements.)

NET CONTENTS:

Sanitizing: To sanitize porous or non-porous surfaces.

1/2 oz. per gallon use-level: The broad spectrum of activity has been evaluated in the presence of 5% soil. Use-Dilution Test.

Pseudomonas aeruginosa • Staphylococcus aureus • Klebsiella pneumoniae • Enterobacteriaceae • Brevibacterium amyloliquefaciens

A.O.A.C Fungicidal Test: This quaternary ammonium cleaner-disinfectant has been evaluated in the presence of 5% soil. Mildewstat: Performance: At 1/2 oz. per gallon, it effectively inhibits the growth of mold and mildew on various surfaces (as indicated in general instructions above).

Virucidal Performance: At 1/2 oz. per gallon, it is effective in the presence of 10% serum and found to be effective against Type 1 and Type 2 (a member of the virus family of the pox viruses), and Influenza A2 (the Hong Kong strain) on environmental surfaces.

Sanitizing Non-Food Contact Surfaces: At use-level, 30 second contact time, this quaternary ammonium cleaner-disinfectant is effective in waters of up to 600 ppm hardness. In the presence of 5% serum on porous and non-porous surfaces.

***KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES:** WITH BLOOD/BODY FLUIDS in health care facilities, the risk of soiling of inanimate surfaces/objects with blood or body fluids can be assessed. This quaternary ammonium cleaner-disinfectant is effective against HIV Type 1 (HIV-1) (associated with AIDS).

***SPECIAL INSTRUCTIONS FOR CLEANING FACES/OBJECTS SOILED WITH BLOOD:** CONTACT TIME: Leave surface wet for 10 minutes. CLEANING PROCEDURE: Blood and other body fluids should be removed from faces/objects before application of #25 QUATERNARY AMMONIUM CLEANER-DISINFECTANT.

PERSONAL PROTECTION: Clean up shoes and eyes protection.

DISPOSAL OF INFECTIOUS MATERIALS: autoclaved and disposed of according to local regulations.

CODE
1023

JAMES
ST. LOUIS