

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

IAN 17 1995

Genlabs
5568 Schaefer Avenue
Chino, CA 91710

Attention: Robert Munion
Vice President

Subject: Myra-Cyn
EPA Registration No. 37265-10
MOU Compliance Amendment dated September 6, 1994

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you make the labeling changes listed below before you release the product for shipping bearing the amended label.

1. Under "DIRECTIONS FOR USE", revise the statement: "This product is not to be used as a terminal sterilant/high-leveling disinfectant..." to read, "This product is not to be used as a terminal sterilant/high-level disinfectant..."
2. Change Trichophyton interdigitale to read Trichophyton mentagrophytes, everywhere it appears on the label.

A stamped copy of the labeling is enclosed for your records. Submit 5 copies of the final label prior to releasing the product for marketing.

If you have any questions concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely,



Walter C. Francis
Acting Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

MYRA-CYN

CLEANER-DISINFECTANT-DEODORIZER
FUNGICIDAL-GERMICIDAL

ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride.....4.5%

INERT INGREDIENTS:.....95.5%

100.00%

WARNING

KEEP OUT OF REACH OF CHILDREN.

FOR PROFESSIONAL, INSTITUTIONAL AND INDUSTRIAL USE ONLY

SEE RIGHT PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA REG. NO. 37265-10

EPA EST. NO. 37265-CA-01

NET ONE GALLON (3.78 L)

GENLABS

5568 Schaefer Ave., Chino, CA 91710 - (909) 591-8451

CLEANER-DISINFECTANT-

For H

PRECAUTIONARY STATEMENTS

WARNING: Keep out of reach of children.

Do not get in eyes, on skin, or on clothing. If it does get in eyes, on skin, or on clothing, flush with plenty of water for at least 15 minutes. Call a doctor for treatment.

STATEMENT OF PRACTICAL TREATMENT

Use as directed. Do not mix with other cleaning products.

Apply to surfaces to be cleaned. Allow to stand for 10 minutes.

and wash all contaminated clothing with plenty of water. Avoid alcohol. Call a doctor for treatment.

quantity of water. Avoid alcohol. Call a doctor for treatment.

DIRECTIONS

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

labeling

This product is not to be used as a disinfectant on surfaces that (1) are in contact with the bloodstream or normal mucous membranes but which do not otherwise enter normally sterile areas or decontaminate critical or semi-critical disinfection.

Apply MYRA-CYN to walls, floors and frames with a cloth or mop. For heavy soiling, use a brush.

For Hospitals & Nursing Homes, add 2 ounces per gallon use-level.

At two ounces per gallon use-level, effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and other pathogenic fungi. Germicidal performance confirmed by the AOAC Use-Dilution Test against *T. interdigitalis* by the AOAC Full Test.

For Schools, Institutional and Industrial use, add 1 ounce per gallon use-level.

At one ounce per gallon use-level, MYRA-CYN is effective against *T. interdigitalis*.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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

37265-10

BEST AVAILABLE COPY

MYRA-CYN
CLEANER-DISINFECTANT-DEODORIZES-FUNGICIDE-GERMICIDAL

For Hospitals and Institutions

CAUTIONARY STATEMENTS HAZARDOUS TO HUMANS AND DOMESTIC ANIMALS

Keep out of reach of children. Causes eye damage and skin irritation. Do not use on skin, or on clothing. Harmful if swallowed. Avoid contamination of food.

MODE OF PRACTICAL TREATMENT: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. For eyes, call a physician. Remove all contaminated clothing before reuse. If swallowed, drink promptly a large glass of water. Avoid alcohol. Call a physician immediately.

DIRECTIONS FOR USE

Use in accordance with the instructions of Federal Law to use this product in a manner inconsistent with its

It is not to be used as a terminal sterilant/high-leveling disinfectant on any instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or enter normally sterile areas of the body. This product may be used to preclean reusable critical or semi-critical medical devices prior to sterilization or high-level

Disinfect MYRA-CYN to walls, floors and other hard surfaces such as tables, chairs and beds with a cloth or mop. For heavily soiled areas, a preliminary cleaning may be

In Hospitals & Nursing Homes add two ounces per gallon of water. In homes use one ounce per gallon use-level. MYRA-CYN is effective against Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis, Escherichia coli, and other fungi. Germicidal performance against the first four organisms has been determined by the AOAC Use-Dilution Test. Fungicidal performance was determined by the AOAC Fungicidal Test.

Institutional and Industrial Users: Add one ounce per gallon of water. In homes use one ounce per gallon use-level. MYRA-CYN delivers excellent cleaning and is

germicidal. It is effective against Staphylococcus aureus, Salmonella choleraesuis, Escherichia coli, and Trichophyton interdigital, the athlete's foot fungus. The same AOAC test used above to confirm suitable performance for hospitals were used.

Cross-Contamination is of major housekeeping concern not only in hospitals, but in schools, institutions, and industry. MYRA-CYN is formulated for this problem area. It both cleans and disinfects effectively when used as directed. Its hard surface disinfecting action will reduce the hazard of cross-contamination.

Two ounces of MYRA-CYN per gallon of water will deodorize bathrooms, garbage storage areas, and other areas where bacterial growth can cause mal odors.

DISINFECTING: Before disinfecting, pre-clean surfaces as directed above. Then prepare 2 oz. of MYRA-CYN per gallon of water and thoroughly wet surface to be disinfected. The disinfecting solution must contact the surface for 10 minutes for proper disinfection. If desired, the surfaces may then be rinsed with clear water or wiped with a clean, damp cloth.

FOR PROFESSIONAL, INSTITUTIONAL AND INDUSTRIAL USE ONLY

STORAGE AND DISPOSAL

STORAGE: Store in a cool, dry place away from any moisture or direct sunlight. Do not stack over 4 cases high. Open containers carefully followed by immediate closure once diluted. If leaked or spilled, soak up material separate and away from other pesticides, fertilizer, food and feed.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited. Pesticide, spray mixture, or rinse water that cannot be used according to Federal or approved State procedures under subtitle C of the Resource Conservation and Recovery Act. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Do not reuse empty container. Plastic Containers: Triple rinse (or equivalent) then offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if allowed by state and local authorities. If burned, stay away from smoke.

BEST AVAILABLE