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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 9 1995

Carroll Company
2900 West Kingsley Road
Garland, TX 75041

Attention: Joyce E. Kenworthy
Regulatory Affairs Specialist

Subject: Single Phenolic Hospital Disinfectant
EPA Registration No. 4313-66
MOU Compliance Amendment dated December 23, 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 the Direction For Use, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling" should be separate from the text below it. Therefore, the sentence beginning with "For disinfecting..." should begin a new paragraph.
2. Identify the strain for Influenza A₂, and the type of Herpes Simplex virus.
3. Under the "Directions For Use", remove the wording "including tuberculous areas."

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 question concerning this letter, please contact Wanda Mitchell at (703) 305-6141.

Sincerely yours,



Ruth G. Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

SINGLE PHENOLIC HOSPITAL DISINFECTANT

GERMICIDE - DETERGENT

BACTERICIDAL - PSEUDOMONACIDAL - TUBERCULOCIDAL
FUNGICIDAL - *VIRUCIDAL

KEEP OUT OF REACH OF CHILDREN
DANGER

See right panel for additional precautions.

ACTIVE INGREDIENT	
O-benzyl-P-chlorophenol	9.72%
INERT INGREDIENTS	90.28%

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAK 3 1995

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
amended, for the pesticide
registered under EPA Reg. No.
4313-66

BEST AVAILABLE

Chemical Specialties

ROLL

CARROLL

CARROLL

CARROLL

**PRECAUTIONARY STATEMENTS
HAZARD TO HUMANS AND DOMESTIC ANIMALS**

**DANGER! CORROSIVE. CAUSES EYE DAMAGE
AND SKIN IRRITATION.**

HARMFUL IF SWALLOWED. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling.

FIRST AID: 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 including shoes before reuse. If irritation persists, consult a physician.

IF SWALLOWED, drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. **DO NOT INDUCE VOMITING.** Call a physician immediately.

NOTE TO PHYSICIANS: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be needed.

PHYSICAL OR CHEMICAL HAZARD

COMBUSTIBLE. Do not store near heat or flame. In case of

FIRE: Use water spray, sodium bicarbonate, or CO₂.

SPILL OR LEAK: Flush area with water spray.

DIRECTIONS FOR USE — It is a violation of federal law to use this product in a manner inconsistent with its labeling. For disinfecting environmental surfaces in hospitals, including tuberculous areas, apply a freshly prepared 1:128 solution (1 oz. per U.S. gallon of water) to pre-cleaned environmental surfaces such as walls, floors, bathroom fixtures, and equipment. Apply using normal methods such as cloth, mop, or mechanical equipment. Thoroughly wet surfaces and allow to remain wet for ten minutes.

Remove all litter and gross filth from surfaces prior to application of solution. Apply the disinfecting solution and keep surfaces wet for at least 10 minutes.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or 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 otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

Formulated for hospital use, this product is tuberculocidal, pseudomonacidal, staphylocidal, and fungicidal. Also virucidal against Herpes simplex, Vaccinia, Influenza A₂, Adenovirus Type 4, when used as directed, on hard, nonporous, inanimate surfaces.

GERMICIDAL QUALIFICATION-AOAC

Use-Dilution Confirmation Test	
Staphylococcus aureus	1:128
Salmonella choleraesuis	1:128
Pseudomonas aeruginosa	1:128
Escherichia coli	1:128

TUBERCULOCIDAL ACTIVITY TEST-AOAC

Remove gross filth or heavy soil and thoroughly clean surface prior to application of product. Effective in 10 minutes at 20 degrees C.

Mycobacterium tuberculosis, var. bovis (BGG)	1:128
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***VIRUCIDAL QUALIFICATION**

Influenza A ₂	1:128
Herpes simplex	1:128
Adenovirus Type 4	1:128
Vaccinia	1:128

FUNGICIDAL TEST-AOAC

Trichophyton mentagrophytes	1:128
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STORAGE AND DISPOSAL: DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL.

STORAGE: Keep container closed when not in use. Do not store near heat or open flame.

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: Plastic Containers—Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

EPA Reg. No. 4313-66

EPA Est. 4313-TX-1

1 U.S. GALLON/3.8 LITERS

CARROLL COMPANY • 2900 W. Kingsley Rd. • Garland, Texas 75041 •

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