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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 6 1995

WEXFORD LABS, INC. 325 Leffingwell Avenue Kirkwood, MO 63122

Attention: Said I. Raziq

Director of Research

Subject:

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Ready to Use Topps

EPA Registration No. 34810-22

MOU Compliance Amendment dated July 31, 1995

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

1. Remove surgical instruments form the list of items which can be disinfected with this product. Surgical items are critical medical devices and must be sterilized.

A stamped copy is enclosed for your records. Submit five (5) copies of the final printed label prior to release of the product for shipment.

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

Sincerely,

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

CONCURRENCES								
SYMBOL								
SURNAME	*****						.,,	
DATE					••••			

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

READY TO USE TOPPS

GERMICIDAL DETERGENT
CLEANS • DISINFECTS • DEODORIZES
GERMICIDAL, PSEUDOMONACIDAL,
TUBERCULOCIDAL, FUNGICIDAL and VIRUCIDAL*

EPA REG. NO. 34810-22 ● EPA EST. NO. 34810-mo-1
KEEP OUT OF REACH OF CHILDREN
CAUTION

GERMICIDAL ACTIVITY: (AOAC Use Dilution Continuation in the presence of 5% serum.) Ps. aeruginosa, S. aureus, S. choleraesuis; including S. sureus (MRSA) (TNSR) (GRM) and (PR) and S. Epidermidis (MRSE). TUBERCULOCIDAL ACTIVITY: (AOAC M. tuberculosis in the presence of 5% serum at 20°C for 10 minutes) FUNGICIDAL ACTIVITY: (AOAC T. Mentagrophytes in the presence of 5% serum.) VIRUCIDAL ACTIVITY; (*influenze A3[Hong Kong], Adenovirus Type 2, Herpes simplex Types 1 & 2, Vaccinia virus in the presence of 5% serum, and HIV-1 [AIDS] in the presence of 10% serum on manimate surfaces.

READY TO USE TOPPS is used for one-step cleaning, disinfecting and deodorizing hard, non-porous inanimate surfaces in Operating Rooms, Intensive Care, Nurseries, Emergency Areas, and Dental Operatories, as well as Police, EMS and other emergency response units. It is a synthetic germicidal detergent with broad spectrum kill of both gram positive and grain negative microorganisms. It is an excellent cleaner.

STORAGE and DISPOSAL: Store at room temperature. Do not leave containers of this product open during storage. Do not reuse empty container, Rinse empty container thoroughly and discard in trash.

√ √Wexford Labs, Inc.

325 Leffingweil Avenue

Contents: One Quart

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent Use READY TO USE TOPPS for all disinfection of hard, inanimate surfaces for working surfaces, surgical instruments, stainless steel, chrome, glass a or by immersing equipment to be disinfected. All hard surfaces must be will least 10 minutes before drying with a cloth. Gross fifth and heavy soil must solution. Discard solution when it becomes dirty and replace with fresh CLEANERS.

DECONTAMINATION OF CRITICAL OR SEMI-CRITICAL DE STERILIZATION/HIGH LEVEL DISINFECTION: This product is not to be a disinfectant on any surface or instrument that (1) is introduced directly in contact with the bloodstream or normally sterile areas of the body, or (2) co which does not ordinarily penetrate the blood barrier or otherwise enter no product may be used to preclean or decontaminate critical or semi-critical or high level disinfection.

*READY TO USE TOPPS KILLS HIV ON PRE-CLEANED ENVIRO PREVIOUSLY SOILED WITH BLOOD/BOD. FLUIDS in all settings in wh soiling of inanimate surfaces/objects with blood or body fluids, and in will soiled with blood or body fluids can be associated with the potential for transvirus type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING S BLOOD AND BODY FLUIDS WHICH MAY CONTAIN HIV-1 (AIDS virus disposable rubber or latex gloves, gowns, face masks, or eye coverings as a cleaning of these surfaces. CONTACT TIME: Leave surfaces wet for 1 .nin other common types of viruses and bacteria. CLEANING PROCEDURE: and clean blood and other body fluids from surfaces and objects before dis off visual soil/clean with solution, and disinfect surface with a second applitude contaminated area should be flooded with the solution before clean solution. DISPOSAL OF INFECTIOUS MATERIAL: Blood and other bod disposed of according to Federal, State and local regulations for infectious

AUGEPTED with COMMENTS in EPA Letter Dated:

NOV 6 1995

Under the Pederal Insecticide, Fungicide and Rodentiside Act as amended, for the resticide registered under the Reg. No.

34810-22