

34810-22

8/26/2003

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August 26, 2003

Mr. Said I, Raziq
Director of Research
WexFord Labs, Inc.
325 Leffingwell Avenue
Kirkwood, MO 63122

Subject: **Ready to Use Toops**
EPA Registration Number 34810-22
Letters Dated February 28, 2003

Dear Mr. Raziq:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended is, acceptable.

Proposed Amendment

- Efficacy data to support new label claims

General Comments:

The submitted efficacy data (MRID No. 458703-01) supports the use of the product, Ready To Use Topps, as a disinfectant with bactericidal activity when tested against *Enterococcus faecalis* (Vancomycin Resistant, ATCC 51575) in the presence of a 5% organic soil load (fetal bovine serum) on hard, non-porous surfaces for a contact time of 10 minutes.

Th submitted efficacy data (MRID No. 458703-02 and 458703-03) support the use of the product, Ready To Use Topps, as a virucidal when tested against Respiratory Syncytial Virus, ATCC VR-26 and Rotavirus, Strain WA in the presence of a 5% organic soil load (fetal bovine serum) on hard, non-porous surfaces for a contact of 10 minutes.

CONCURRENCES

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

Other Comments:

1. All emergency response units must be specified. Delete the statement, "Other emergency response units."

2. Revise the storage disposal statement as follows:

Pesticide Storage: (you must provide specific storage instructions).

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: (Refer to PR Notice 83-3 for appropriate container disposal statement).

3. The following statement must be added to the First Aid Statement:

"Have the product container or label with you when calling a poison control center or doctor, or going for treatment."

4. With respect to HIV Cleaning Procedures, change the Word "decontaminated " to "clean with fresh solution".

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

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Drusilla Copeland at (703) 308-6224.

Sincerely,



Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

Enclosure

READY TO USE TOPPS

GERMICIDAL DETERGENT

CLEANS • DISINFECTS • DEODORIZES

GERMICIDAL, PSEUDOMONACIDAL, TUBERCULOCIDAL,
FUNGICIDAL and VIRUCIDAL* with 5% Serum.

ACTIVE INGREDIENT:

ortho-Phenylphenol0.027%
Thymol0.027%

INERT INGREDIENTS:

.....99.946%
Includes biodegradable detergents and no phosphates 100.000%

EPA REG. NO. 34810-22 • EPA EST. NO. 34810-mo-1

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID

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. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

PRECAUTIONARY STATEMENTS: HAZARD TO HUMANS AND DOMESTIC ANIMALS.

CAUTION: Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

STORAGE AND DISPOSAL: Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Wastes resulting from the use of this product may be disposed of according to applicable Federal, State or local procedures. **PESTICIDE CONTAINER DISPOSAL:** Do not reuse empty container. Wrap container and put in trash.

GERMICIDAL ACTIVITY: (AOAC Use Dilution Confirmation in the presence of 5% serum.) Ps. aeruginosa, S. aureus, S. choleraesuis; including S. aureus (MRSA) and S. Epidermidis (MRSE), Tetracycline, Novobiocin Streptomycin resistant Staphylococcus aureus (TNSR), Gentamicin, Methicillin resistant Staphylococcus aureus (GRM), Penicillin resistant Staphylococcus aureus (PR), and Enterococcus Faecalis (VRE). **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:** (*Influenza A3[Hong Kong], Herpes simplex Types 1 & 2, Vaccinia virus in the presence of 5% serum, Human Rotavirus, and Respiratory Syncytial virus in the presence of 5% serum, and HIV-1 [AIDS] in the presence of 10% serum on hard, non-porous surfaces.



Wexford Labs, Inc.

325 Leffingwell Avenue • Kirkwood, Missouri 63122

Contents: One Quart

DIRECTIONS FOR USE

It is a violation of Federal Law to use the product in a manner inconsistent with its labeling. Use Ready To Use TOPPS for one-step cleaning, disinfecting and deodorizing of hard, non-porous surfaces, in Operating Rooms, Intensive Care, Nurseries, Emergency Areas, Dental Operatories, EMS, and other emergency response units, for working surfaces, stainless steel, chrome, glass and vinyl. Apply with a cloth or brush, or by immersing equipment to be disinfected. All hard surfaces must be wet thoroughly, and remain wet for at least 10 minutes before drying with a cloth. Gross filth and heavy soil must be removed before applying cleaning solution. Discard solution when it becomes dirty and replace with fresh solution. **DO NOT MIX WITH OTHER CLEANERS.**

GENERAL PRECAUTIONS AND RESTRICTIONS

DECONTAMINATION OF CRITICAL OR SEMI-CRITICAL DEVICES PRIOR TO TERMINAL

STERILIZATION/HIGH LEVEL DISINFECTION: 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

*READY TO USE TOPPS KILLS HIV ON PRE-CLEANED ENVIRONMENTAL

SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in all settings in which there is an expected likelihood of soiling of hard, non-porous surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING

SURFACES/OBJECTS SOILED WITH BLOOD AND BODY FLUIDS WHICH MAY CONTAIN HIV-1(AIDS virus). PERSONAL PROTECTION: Wear disposable rubber or latex gloves, gowns, face masks or eye coverings as appropriate, when performing manual cleaning of these surfaces. **CONTACT**

TIME: Leave surfaces wet for 1 minute. This contact time will not control other common types of viruses and bacteria. **CLEANING PROCEDURE:** The solution may be used to remove and clean blood and other body fluids from surfaces and objects before disinfection. For lightly soiled areas wipe off visual soil/clean with solution, and disinfect surface with a second application of the solution. For large spills the contaminated area should be flooded with the solution before cleaning, then decontaminated with fresh solution. **DISPOSAL OF INFECTIOUS MATERIAL:** Blood and other body fluids should be autoclaved and disposed of according to Federal, State and local regulations for infectious waste disposal.

ACCEPTED
with COMMENTS
EPA Letter Dated:

AUG 26 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 34810-22

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