

34810-19

12/08/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

December 8, 2008

Mary Jo Thierry
Operations Manager
Wexford Labs, Inc.
325 Leffingwell
Kirkwood, Missouri 63122

Subject: Revised Label per EPA Letter of 11/25/08
Product Name: TOPPS
EPA Reg. Number: 34810-19
Email Date: 05-Dec-2008
Email Receipt: 08-Dec-2008

Dear Ms. Thierry:

The label amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable. A stamped copy is enclosed for your record.

If you have further questions concerning this letter, please contact me by telephone at (703) 308-6422 or by e-mail at heyward.adam@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read "Adam Heyward".

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

Enclosure: [Stamped label]



TOPPS

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

in soft water or hard water (A.O.A.C. 400 ppm hardness as Calcium Carbonate), with 5% serum, on inanimate surfaces.

ACTIVE INGREDIENTS:

o-Phenylphenol.....7%
Thymol.....7%

INERT INGREDIENTS:.....86%
Includes biodegradable detergents, perfume, and water 100%

EPA REGISTRATION NO. 34810-19 EPA ESTABLISHMENT NO. 34810-MO-1

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See side panel for additional precautionary and first aid statements

Wexford Labs, Inc.

325 Leffingwell Avenue

Kirkwood, Missouri 63122

FOR INDUSTRIAL AND INSTITUTIONAL USE

Contents: One U.S. Gallon (128 Fluid Ounces) or 3.785 Liters

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **DO NOT MIX WITH OTHER CLEANERS.** For all disinfection of hard, nonporous, surfaces in hospitals, health-care facilities, schools, and nursing homes, such as floors, walls, bathroom fixtures, shower stalls, use TOPPS at 1/2 ounce per gallon of water. TOPPS use-dilution may be applied with a cloth, mop or brush on surfaces such as stainless steel, chrome, glass, vinyl, ceramic, and terrazzo. Wet all surfaces thoroughly for at least 10 minutes. **Gross filth and heavy soil must be removed before applying cleaning solution. When used for mopping or from an open pail, solution should be changed at least daily or more often if the solution becomes diluted or soiled.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store at room temperature. Do not leave container of this product open during storage.

PESTICIDE DISPOSAL: Open dumping is prohibited. Pesticide wastes are acutely hazardous.

IMPORTANT: Disposal of excess pesticides, spray mixture or rinsate is a violation of Federal Law.

PESTICIDE CONTAINER DISPOSAL: Do not reuse empty container. Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill or by incineration, if allowed by state or local authorities. Consult federal, state, or local disposal authorities for approved alternate procedure.

GENERAL INFORMATION

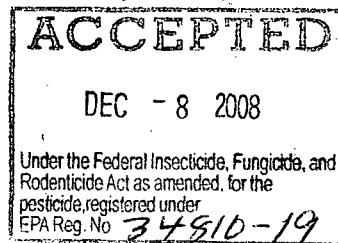
GERMICIDAL QUALIFICATIONS: (AOAC Use Dilution Confirmation) in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum at.....1:256 (AOAC Ps. aeruginosa, S. aureus, S. choleraesuis including S.aureus [MRSA] [TNSR] [GRM] and [PR] and S. Epidemidis [MRSE]).

TUBERCULOCIDAL ACTIVITY TEST: (AOAC M. tuberculosis) in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum (at 20° C for 10 minutes) at.....1:256

FUNGICIDAL TEST: (AOAC T. mentagrophytes) in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum at.....1:256

VIRUCIDAL ACTIVITY TEST: (*Influenza A₂ [Hong Kong], Herpes Simplex Types 1 and 2, and Vaccinia virus) in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum, and HIV-1 [AIDS virus] in the presence of 400 ppm hardness and 10% serum, on inanimate surfaces, at.....1:256

Made in U.S.A



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TOPPS

CONCENTRATED GERMICIDAL DETERGENT

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.

***TOPPS KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling of inanimate 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: TOPPS 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 TOPPS solution, and disinfect surface with a second application of the TOPPS solution. For large spills the contaminated area should be flooded with the TOPPS solution before cleaning, then decontaminated with fresh TOPPS solution.

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS. DANGER. KEEP OUT OF REACH OF CHILDREN. CORROSIVE. Causes irreversible eye damage. Harmful if absorbed through the skin. Do not get in eyes or on clothing. Avoid contact with skin. Wear goggles or face shield. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

FIRST AID: IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control or doctor for treatment advice.

IF ON SKIN: Take off contaminate clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measurements against circulatory shock, respiratory depression and convulsion may be needed. *(Have the product container or label with you when calling a poison control center or doctor or going for treatment)*

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.

Wexford Labs, Inc.

WC-TOPPS-053002