

32 34810-6 1045
 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: Wex-cel Concentrated Germicidal Detergent
 EPA Registration No. 34810-6
 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 changes listed below before you release the product for shipment bearing the amended label.

1. Under the heading "Virucidal Activity*" remove the statement "(AOAC Use Dilution Confirmation)".
2. Remove surgical instruments from the list of surfaces to be disinfected. Surgical instruments 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,



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

CONCURRENCES

SYMBOL								
SURNAME								
DATE								



WEX-CEL

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

In soft or hard water, (A.O.A.C. 400 ppm Hardness as Calcium Carbonate)

ACTIVE INGREDIENTS:

Sodium ortho-Phenylphenate 6.49%

Sodium ortho-Benzyl-para-Chlorophenate 6.50%

INERT INGREDIENTS: 87.01%

100.00%

EPA REGISTRATION NO. 34810-6

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See rear 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 Fl. oz.) or 3.785 Liters

GERMICIDAL QUALIFICATIONS:

(A.O.A.C. Ps. aeruginosa, S. aureus, S. choleraesuis) in the presence of

TUBERCULOCIDAL ACTIVITY TEST:

(A.O.A.C. M. tuberculosis) in the presence of 400 ppm water hardness

FUNGICIDAL TEST:

(A.O.A.C. Trichophyton mentagrophytes) in the presence of 400 ppm

VIRUCIDAL ACTIVITY TEST:

*Influenza A2, Herpes Simplex, Adenovirus Type 5, and Vaccinia virus (Confirmation) in the presence of 400 ppm water hardness, in the presence of 400 ppm hardness as Calcium Carbonate and 5%

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS. DANGER. Keep Out of Reach of Children. Corrosive. Causes eye damage and severe skin irritation. Avoid breathing dust, fumes, or vapors. Avoid contact with skin, eyes, or clothing. If swallowed, avoid contamination of food.

STATEMENT OF PRACTICAL TREATMENT: In case of contact (immerse) with plenty of water for at least 15 minutes. For eyes call a physician immediately. If swallowed, drink promptly a large amount of water or alcohol and call a physician.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate measures against circulatory shock, respiratory depression and convulsions.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Do not reuse empty container. Triple rinse (or equivalent), then offer to recycling or dispose of in a sanitary landfill or by incineration, if allowed. Consult federal, state or local disposal authorities for approved methods.

FOR DISINFECTION IN FOOD PROCESSING PLANTS

WEX-CEL is suitable for cleaning floors, walls and equipment in all plants at 1:128 dilution. Cover or remove all food packaging material. Saturate all surfaces with the use-dilution. Scrub to loosen all soil. Thoroughly rinse all wetted and cleaned surfaces with potable water.

Made in U.S.A.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 6 1995

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

34810-6

3-3

WEX-CEL

CONCENTRATED GERMICIDAL DETERGENT

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.

WEX-CEL is a synthetic germicidal detergent with broad spectrum kill of both gram positive and gram negative microorganisms. For all disinfection, including hospital and health-care facilities, schools, and nursing homes, use WEX-CEL at a dilution of 1 ounce per gallon of water for walls, floors, bathroom fixtures, surgical instruments, stainless steel, chrome, glass and vinyl. WEX-CEL may be applied with a cloth, mop, or brush, or by immersing equipment to be disinfected. Wet all surfaces thoroughly. Allow to remain wet for 10 minutes. Then wipe dry or let air dry. Gross filth and heavy soil must be removed before applying cleaning solution.

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.

*WEX-CEL KILLS HIV-1 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 surface/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: WEX-CEL solution may be used to remove and clean blood and other body fluids from surface and objects before disinfection. For lightly soiled areas wipe off visual soil/clean with WEX-CEL solution, and disinfect surface with a second application of the WEX-CEL solution. For large spills the contaminated area should be flooded with the WEX-CEL solution before cleaning, then decontaminated with fresh WEX-CEL 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.

Wexford Labs, Inc.

EPA ESTABLISHMENT NUMBER 34810-MO-1

WC-101794