

SEP 30 1992

Mr. Said I. Raziq  
Wexford Labs, Inc.  
325 Leffingwell Avenue  
Kirkwood, MO 63122

Dear Mr. Raziq:

Subject: WEX-CEL  
EPA Registration No. 34810-6  
PHENEX-CEL  
EPA Registration No. 34810-16  
Your Amendments Dated April 29, 1992

This is in response to your amendments of the above date requesting to add a label claim of effectiveness against HIV-1 ((AIDS Virus) in 400 ppm hard water and 5% blood serum at a contact time of 1 minute.

The submitted virucidal data meet the efficacy requirements in support of these products effectiveness against HIV-1 (AIDS virus) when used on hard, nonporous, inanimate surfaces in the presence of a moderate amount of organic soil (fetal 5%-bovine serum) when used at a dilution of 1:128 in 418.5 ppm of hard water for a contact time of 1.0 minute at room temperature (20-25 °C).

The labelings referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are acceptable subject to the comments listed below. Stamped copies are enclosed for your records. Five copies of the finished labeling must be submitted before you release the product for shipment bearing the amendment labeling.

1. WEX-CEL, EPA Registration No. 34810-6

- a. Under the directions for use and right panel, the wording ". . .WEX-CEL KILLS HIV ON PRE-CLEANED . . ." must be revised to read ". . . WEX-CEL KILLS HIV-1 ON PRE-CLEANED . . ."

62977:I:WP50:Pringle:WP32-3:KEVRIC:09/23/92:10/21/92

R:62980:WP50:Pringle:WP32-3:KEVRIC:09/30/92:10/29/92

CONCURRENCES

|         |          |  |  |  |  |  |  |
|---------|----------|--|--|--|--|--|--|
| SYMBOL  | Wt 75040 |  |  |  |  |  |  |
| SURNAME | Pringle  |  |  |  |  |  |  |
| DATE    | 9-30     |  |  |  |  |  |  |

- b. The ingredients "Sodium Dodecyl benzene sulfonate and Tetrasodium ethylenediamine tetracetate" must be removed from the active ingredient listings and added to the inert ingredient listings.

2. PHENEX-CEL, EPA Registration No. 34810-16

- Under the directions for use and upper right back panel, the wording "PHENEX-Cel KILLS HIV ON PRE-CLEANEL . . ." must be revised to read "PHENEX-CEL KILLS HIV-1 ON PRE-CLEANED . . . ."

If you have any further questions, please contact Ms. Barbara Pringle at (703) 305-6484.

Sincerely yours,



Ruth G. Douglas  
Product Manager (32)  
Antimicrobial Program Branch  
Registration Division (H7505C)

Enclosures



# 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%
- Sodium Dodecyl Benzene Sulfonate ..... 1.40%
- Tetrasodium Ethylenediamine Tetraacetate ..... 1.21%

**INERT INGREDIENTS:** ..... 84.40%  
100.00%

EPA REGISTRATION NO. 34810-6

**DANGER: KEEP OUT OF REACH OF CHILDREN**

see rear panel for additional precautionary and first aid statements.

## Wexford Labs, Inc.

325 Leffingwell Avenue

Kirkwood, Missouri 63122

**GERMICIDAL QUALIFICATIONS:**

(A.O.A.C. Ps. aeruginosa, S. aureus, S. choleraesuis) in the presence of 400 ppm hardness as Calcium Carbonate

**TUBERCULOCIDAL ACTIVITY TEST:**

(A.O.A.C. M. Tuberculosis) in the presence of 400 ppm water hardness as Calcium Carbonate

**FUNGICIDAL TEST:**

(A.O.A.C. Trichophyton mentagrophytes) in the presence of 400 ppm water hardness as Calcium Carbonate

**VIRUCIDAL ACTIVITY TEST:**

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

**PRECAUTIONARY STATEMENTS:**

**HAZARD TO HUMANS AND DOMESTIC ANIMALS. DANGER - Corrosive.** Causes eye damage and severe skin irritation. Avoid contact with eyes, on skin, or on clothing. Protect eyes and skin when handling. If swallowed, avoid contamination of food.

**STATEMENT OF PRACTICAL TREATMENT:** In case of contact with plenty of water for at least 15 minutes. For eyes call contaminated clothing before reuse. If swallowed, drink prompt alcohol and call a physician.

**NOTE TO PHYSICIAN:** Probable mucosal damage may occur. Measures against: circulatory shock, respiratory depression and

**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 for reuse or dispose of in a sanitary landfill or by incineration, if allowed. Consult federal, state or local disposal authorities for approved procedures.

**FOR DISINFECTION IN FOOD PROCESSING:**

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

**ACCEPTED FOR REGISTRATION BY MAINTENANCE PERSONNEL ONLY**  
Net Contents: One U.S. Gallon  
EPA Letter Detail

SEP 20 1980  
Under the Federal Insecticide, Fungicide, and Rodenticide Act, registered for sale and distribution under EPA Reg. No. 34810-6

**BEST AVAILABLE COPY**

# WEX-CEL

## CONCENTRATED GERMICIDAL DETERGENT

WEX-CEL is used for cleaning, disinfecting and deodorizing floors, walls and other similar hard surfaces. Especially suited for use in Operating Rooms, Intensive Care, Nurseries, Emergency Areas, Patient Rooms and Rest Rooms.

WEX-CEL is a synthetic germicidal detergent with broad spectrum kill of both gram positive and gram negative microorganisms. It is an excellent cleaner which dilutes clear (1:128) in soft or hard water up to 400 ppm hardness, contains biodegradable detergents and is phosphate free. DO NOT MIX WITH OTHER CLEANERS.

### DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

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.

When disinfecting surgical instruments with WEX-CEL these instruments must be pre-cleaned to remove blood and serous exudates prior to immersion in, or treatment with WEX-CEL. Discard solution when it becomes dirty and replace with fresh solution.

**\*WEX-CEL 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 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

**BEST AVAILABLE COPY**