

SEP 10 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

Pringle 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-CLEANED . . ." 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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 30 1982

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the

34810-16



PHENEX-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) and
organic soil (5% serum);

ACTIVE INGREDIENTS:

o-Phenylphenol, sodium salt 2.45%

o-Benzyl-p-Chlorophenol, sodium salt 7.15%

INERT INGREDIENTS: 84.40%

100.00%

EPA REGISTRATION NO. 34810-16

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See side panel for additional precautionary statements

Wexford Labs, Inc.

325 Leffingwell Avenue

Kirkwood, Missouri 63122

FOR INDUSTRIAL AND INSTITUTIONAL USE

Contents: One U.S. Gallon (128 Fl. Ozs)

BEST AVAILABLE

GERMICIDAL QUALIFICATIONS:

A O A C: Ps. aeruginosa, S. aureus, S. choleraesuis; in the presence of Calcium Carbonate and 5% serum at 100°C for 10 minutes.

TUBERCULOCIDAL ACTIVITY TEST:

(A O A C M) Tuberculosis in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum at 100°C for 10 minutes.

FUNGICIDAL TEST:

(A O A C) Trichophyton mentagrophytes in the presence of Calcium Carbonate and 5% serum at 100°C for 10 minutes.

VIRUCIDAL ACTIVITY TEST:

Influenza A3 Hong Kong, herpes Simplex Type 2, Adenovirus 14; (A O A C) Use Dilution Confirmation; and HIV1 / AIDS virus in the presence of Calcium Carbonate and 5% serum at 100°C for 10 minutes.

PRECAUTIONARY STATEMENT

HAZARD TO HUMANS AND DOMESTIC ANIMALS. DANGER
Corrosive. Causes eye damage and skin irritation. Avoid breathing dust, fumes or clothing. Protect eyes and skin when handling. 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 promptly and call a physician.

NOTE TO PHYSICIAN: Probable mucosa damage may contribute to respiratory 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 disposal in a sanitary and/or by incineration, if allowed. Consult federal, state or local disposal authorities for approval.

BEST AVAILABLE COPY

PHENEX-CEL CONCENTRATED GERMICIDAL DETERGENT

PHENEX-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. PHENEX-CEL is a synthetic germicidal detergent with broad spectrum kill of both gram positive and gram negative microorganisms. It is an excellent cleaner, 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 of hard surfaces in hospitals, health-care facilities, schools and nursing homes, such as floors, walls, bathroom fixtures, shower stalls and surgical instruments, use PHENEX-CEL at 1 ounce per gallon of water. PHENEX-CEL 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 ten minutes. Use-dilution of PHENEX-CEL should be changed daily, or sooner if it becomes over diluted or soiled. For gross filth or heavy soil a pre-cleaning step is required.

When disinfecting surgical instruments with PHENEX-CEL, these instruments must be thoroughly pre-cleaned to remove blood and serous exudates, rinsed and rough dried, prior to immersion in, or treatment with PHENEX-CEL.

***PHENEX-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 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: PHENEX-CEL 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 PHENEX-CEL solution, and disinfect surface with a second application of the PHENEX-CEL solution. For large spills the contaminated area should be flooded with the PHENEX-CEL solution before cleaning, then decontaminated with fresh PHENEX-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

PC 051492