

SEP 10 1992

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

Dear Mr. Raziq:

Subject: Super WEX-CEL  
EPA Registration No. 34810-7  
Your Amendment Dated April 29, 1992

This letter is in response to your amendment request of the above date to add a label claim for 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 the product effectiveness against HIV-1 (AIDS virus) when used on hard, nonporous, inanimate surfaces in the presence of a moderate amount of soil (5% fetal bovine serum) when used at a dilution of 1:256 in 418.50 ppm of hard water for a contact time of 1.0 minute at room temperature (20-25 C).

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

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

*Pringle 9/1/92*

62976:I:WP50:Pringle:WP32-3:KEVRIC:09/22/92:10/17/92  
R:62979:WP50:Pringle:WP32-3:KEVRIC:09/24/92:10/23/92  
R:62980:WP50:Pringle:WP32-3:KEVPIC:09/30/92:10/29/92

CONCURRENCES

SYMBOL	SURNAME	DATE					

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)**

**Enclosure**



# SUPER 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 ..... 13.27%  
Sodium ortho-Benzyl-para-Chlorophenate ..... 13.02%

**INERT INGREDIENTS:** ..... 73.71%  
..... 100.00%

EPA REG. NO. 34810-7

**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.)

**GERMICIDAL QUALIFICATIONS:**

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

**TUBERCULOCIDAL ACTIVITY TEST:**

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

**FUNGICIDAL TEST:**

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

**VIRUCIDAL ACTIVITY TEST:**

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

**PRECAUTIONARY STATEMENT**

**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 contraindicate. 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. Thoroughly rinse (or equivalent), then store 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 PLANTS**

SUPER WEX-CEL is suitable for cleaning floors, walls and equipment in food processing plants at 1:255 dilution. Cover or remove all food and debris. Saturate all surfaces with the use dilution. Scrub thoroughly. Thoroughly rinse all wetted and cleaned surfaces.

**ACCEPTED  
with COMMENTS  
EPA Letter Dated  
SEP 30 1982**

**BES**

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

34810-7

## **SUPER WEX-CEL**

### **CONCENTRATED GERMICIDAL DETERGENT**

SUPER 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. SUPER WEX-CEL is a synthetic germicidal detergent with broad spectrum kill of both gram positive and gram negative microorganisms, an excellent cleaner which dilutes clear (1:256) 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 SUPER WEX-CEL at a dilution of 1/2 ounce per gallon of water for walls, floors, bathroom fixtures, surgical instruments, stainless steel, chrome, glass and vinyl. SUPER 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 SUPER WEX-CEL these instruments must be precleaned to remove blood and serous exudates prior to immersion in, or treatment with, SUPER WEX-CEL. Discard solution when it becomes dirty and replace with fresh solution.

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

SNC061292

**BEST AVAILABLE COPY**