UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1045

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			
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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%
	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. choleraesurs) in the presence:

TUBERCULOCIDAL ACTIVITY TEST:

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

FUNGICIDAL TEST:

(A.C.A.C. Trichophyton mentagrophytes) in the presence of 400 ppm VIRUCIDAL ACTIVITY TEST:

*Influenza A2, Herpes Simplex, Adenovirus Type 5, and Vaccinia vi 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, Kee Cottosne. Causes eye damage and severe skin initiation. Avoid prest in eyes, on skin, or on clothing. Protect eyes and skin when handling or if swallowed. Avoid contamination of tood.

STATEMENT OF PRACTICAL TREATMENT: In case of contect imm with planty of water for at least 15 minutes, For eyes cett a physician contaminated clothing before reuse. If swallowed, drink promptly a lat alcohol and call a physician.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindict

Measures against circulatory shock, respiratory depression and conv

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposes. Op not reuse empty container. Triple rinse for adulyations, then offer to or dispose of in a sanitary tandfill or by incineration, if allowed * Consult federal, state or local disposel authorities for approved att.

FOR DISINFECTION IN FOOD PROCES

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

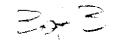
Mede in U.S.A.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 6 1995

Under the course Insecticide, Functional, and Rod whiche Act as amended, for the posticide windred under FPA Reg. No.

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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 fifth 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.