UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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

SUBJECT: WEX-CIDE

EPA Registration No. 34810-8 Amendment of March 17, 1993

This is response to your request to amend this registration to add the virucidal claim against Human Rotavirus Wa Strain (ATCC 2018). The following comments apply.

The submitted data are acceptable to support effectiveness of this product as a virucide against Human Rotavirus WA Strain (ATCC-2018) at a 1:256 dilution (1/2 ounce product/gallon of water) on hard, non-porous surfaces in the presence of 5% blood serum and 400ppm CaCO3 hard water for a contact time of 10 minutes at room temperature.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act is acceptable. Submit five copies of the finished label before you release the product for shipment bearing the amended labeling.

Please note that this labeling must comply with PR Notice 94-4 within the timeframe indicated in that Notice.

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

Sincerely,



Ruth G. Douglas
Product Manager 32
Antimicrobial Program Branch

		CONCURRENCES CONCURRENCES							
SYMBOL	7505C-								
SURNAME		/			****	***********	*************	***********	
STAC	10-17				*****				

EPA Form 1320-1A (1/90)

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WEX-CIDE

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:

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ortho-Phenylphenol 6.73% ortho-Benzyl-para-Chlorophenol 5.76% INERT INGREDIENTS: 87.51% 100.00%

EPA REGISTRATION NO. 34810-8

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 Fi. Ozs.)

GERMICIDAL QUALIFIC (AOAC Use Dilution Confirmation

and 5% serum at (AOAC Ps. aeruginosa, S. aureus and [PR] and S. Epidermedis [Mi **TUBERCULOCIDAL ACT**

(AOAC M. Tuberculosis) in the 5% serum at (20°C for 10 minutes **FUNGICIDAL TEST:**

(AOAC T. mentagrophytes) in th 5% serum at

VIRUCIDAL ACTIVITY TE (*Influenza A3 [Hong Kong], Ade Human Rotavirus, in the presenc-In the presence of 400 ppm hards

PREC

FAZARD TO HUMANS AND DO Corrosive. Causes eye damage of on skin, or on clothing. Wear g concentrate. Harmful if swallowed STATEMENT OF PRACTICAL T with plenty of water for at least contaminated clothing before realcohol and call a physician, NOTE TO PHYSICIAN: Probable

Measures against circulatory sho

Do not contaminate water, food o not reuse empty container. Triple or dispose of in a sanitary lands Consult federal, state or local dis

CONCENTRATED GERMICIDAL DETERGENT

WEX-CIDE is used for one-step 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-CIDE is a synthetic germicidal detergent with broad spectrum kill of both gram positive and gram negative micro-organisms. 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, use WEX-CIDE at a dilution of 1/2 cunce per gallon of water for walls, floors, bathroom fixtures, surgical instruments, stainless steel, chrome, glass and vinyl. WEX-CIDE solution may be applied with a cloth, mop or brush, or by immersing equipment to be disinfected. Wet all surfaces thoroughly. The surface must remain wet for at least 10 minutes before drying with a cloth, or a mop in the case of floors. Gross filth and heavy soil must be removed before applying cleaning solution. When used for mopping or from an open pail, solution should be changed at least daily or more often if the solution becomes diluted or soiled. WEX-CIDE is suitable for cleaning floors and walls in all departments of food processing plants at 1:256 use dilution.

DISINFECTING SURGICAL INSTRUMENTS: These instruments must be thoroughly precleaned to remove blood and serous exudates, rinsed and rough dried prior to immersion in, or treatment with WEX-CIDE.

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

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