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 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 6 1995

WEXFORD LABS, INC.
 325 Leffingwell Avenue
 Kirkwood, MO 63122

Attention: Said I. Raziq
 Director of Research

Subject: Ultra
 EPA Registration No. 34810-28
 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 change listed below before you release the product for shipment bearing the amended label.

1. Remove surgical instruments form the list of items which can be disinfected with this product. Surgical items 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						



ULTRA

**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:	
ortho-Phenylphenol	10.10%
ortho-Benzyl-para-Chlorophenol	8.64%
INERT INGREDIENTS:	81.26%
	<u>100.00%</u>

EPA REGISTRATION NO. 34810-28

**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 Fluid Ounces) or 3.785 Liters

GERMICIDAL QUALIFICATIONS:

(AOAC Use Dilution Confirmation) in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum at
(AOAC Ps. aeruginosa, S. aureus, S. choleraesuis; including S. aureus [MRSA] and [PR] and S. Epidermidis [MRSE]).

TUBERCULOCIDAL ACTIVITY TEST:

(AOAC M. tuberculosis) in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum at (20°C for 10 minutes)

FUNGICIDAL TEST:

(AOAC T. mentagrophytes) in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum at

VIRUCIDAL ACTIVITY TEST:

(*Influenza A₃ [Hong Kong], Adenovirus Type 2, Herpes simplex Types 1 and 2, and HIV-1 [AIDS virus]) in the presence of 400 ppm hardness as Calcium Carbonate and 10% serum at

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS. DANGER. Keep out of reach of children. Corrosive. Causes eye damage or skin irritation. Avoid breathing spray mist. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling concentrate. Harmful if swallowed.

STATEMENT OF PRACTICAL TREATMENT: In case of contact immediately flush with plenty of water for at least 15 minutes. For eyes call a physician. Remove contaminated clothing before reuse. If swallowed drink promptly a large quantity of water or alcohol and call a physician.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of epinephrine. Measures against circulatory shock, respiratory depression and convulsion may be necessary.

STORAGE AND DISPOSAL

Store at room temperature. Do not leave containers of this product open during use. Clean thoroughly. Do not reuse empty containers, wrap and put in trash.

Made in U.S.A.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 6 1995

ULTRA is a disinfectant, detergent, and fungicide. It acts as a general purpose disinfectant and is registered under EPA Reg. No.

34810-28

3-13

ULTRA

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. For all disinfection of hard surfaces in hospitals, health-care facilities, schools, and nursing homes, use ULTRA at a dilution of 1/3 ounce per gallon of water for walls, floors, bathroom fixtures, surgical instruments, stainless steel, chrome, glass and vinyl. ULTRA 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. Discard solution when it becomes dirty and replace with fresh solution. ULTRA is suitable for cleaning floors and walls in all departments of food processing plants at 1:384 use dilution.

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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

***ULTRA 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). Wear rubber or latex gloves when performing manual cleaning of these surfaces. **CONTACT TIME:** Leave surfaces wet for 10 minutes.

CLEANING PROCEDURE: ULTRA solution may be used to remove blood and other body fluids from surfaces and objects. For lightly soiled areas wipe off visual soil with ULTRA solution, and disinfect surface with a second application of the ULTRA solution. For large spills the contaminated area should be flooded with the ULTRA solution before cleaning, then decontaminated with fresh ULTRA 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

UL-101794