

34810-21

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 8, 2009

Mary Ann Auer
CEO
Wexford Labs, Inc.,
325 Leffingwell Ave.
Kirkwood, Missouri 63122

Subject: **Ready-To-Use Wex-Cide**
EPA Registration Number: 34810-21
Letter Dated: September 23, 2008
Receipt Date: September 24, 2008

Dear Ms. Auer:

The following amendment, submitted in connection with registration under section 3(c) (7) (A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the following comments.

Proposed Amendment

- Added efficacy claim (Rhinovirus Type 37)

Labeling Comments

- Please change "*Salmonella choleraesuis*" to read "*Salmonella enterica*". The ATCC has changed the nomenclature for this organism.

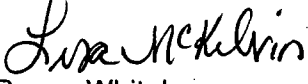
General Comment

The Agency is moving away from review of paper submitted registration applications to electronic review of applications. Therefore, we need your help to make this an efficient and convenient process for both you and the Antimicrobials Division. Accordingly, we are asking you to submit future labeling amendments for this product via the electronic labeling process. Refer to the following website for guidance on electronic submissions, including label: http://www.epa.gov/oppfead1/eds/esr_guidance.htm#overallsub.

If you have any questions concerning electronic label submissions, a list of contacts is available at the following website: <http://www.epa.gov/oppfead1/eds/edsgoals.htm#contacts>.

Should you have further questions concerning this letter, please contact me by telephone at (703) 308-7003 or by e-mail at whitaker.renae@epa.gov or Lisa McKelvin by telephone at (703) 308-7496 or by email at mckelvin.lisa@epa.gov during the hours of 8:00 am to 4:00 pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,


for Renae Whitaker
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

READY TO USE WEX-CIDE

[One-Step Disinfectant Cleaner and Deodorizer]

**GERMICIDAL DETERGENT
CLEANS • DISINFECTS • DEODORIZES
GERMICIDAL, PSEUDOMONACIDAL,
TUBERCULOCIDAL,
FUNGICIDAL and VIRUCIDAL***

[Effective against MRSA, Staph, HIV and more
Formulated for sports hygiene]

ACTIVE INGREDIENTS:

ortho-Phenylphenol.....	0.026%
ortho-Benzyl-para-Chlorophenol	0.023%
INERT INGREDIENTS:	<u>99.951%</u>
Includes detergents, perfume and water	
TOTAL	100.000%

EPA REG. NO. 34810-21 • EPA EST. NO. 34810-MO-1

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

See side panel for precautionary statement and first aid

Wexford Labs, Inc.
325 Leffingwell Avenue • Kirkwood, Missouri 63122

Contents: One Quart

GERMICIDAL ACTIVITY: (AOAC Use Dilution Confirmation in the presence of 5% serum.)

Ps. aeruginosa, S. aureus, S. choleraesuis; including S. aureus (MRSA) and S. Epidermidis (MRSE), Enterococcus Faecalis (VRE). **TUBERCULOCIDAL ACTIVITY:** (AOAC M. tuberculosis in the presence of 5% serum at 20° C for 10 minutes) **FUNGICIDAL ACTIVITY:** (AOAC T. Mentagrophytes in the presence of 5% serum.) **VIRUCIDAL ACTIVITY:** (*Influenza A3[Hong Kong], Herpes simplex Types 2, Rhinovirus Type 37, Vaccinia virus, Human Rotavirus, and Respiratory Syncytial virus in the presence of 5% serum, and HIV-1 [AIDS] in the presence of 10% serum on hard, non-porous surfaces.

PRECAUTIONARY STATEMENTS:

HAZARD TO HUMANS AND DOMESTIC ANIMALS –

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

FIRST AID - IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing. Call a Poison Control Center or doctor for further treatment advice

STORAGE AND DISPOSAL: Store at room temperature. Do not leave containers of this product open during storage. Do not reuse empty container. Rinse thoroughly. Wrap container and put in trash.

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JAN 8 2009

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
registered under EPA Reg. No. 34810-21

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Use for all disinfection for hard, non-porous inanimate surfaces in Operating Rooms, Intensive Care, Nurseries, Emergency Areas, Dental Operatories, Athletic Facilities Police, EMS and other emergency response units.

(Note to reviewer: The following is considered optional marketing language)

(Disinfects, cleans and deodorizes the following hard, non-porous inanimate surfaces: floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, plastic surfaces.)

(Use [on] [to clean and disinfect] nonporous athletic mats, wrestling mats, exercise equipment and training tables.)

DIRECTIONS FOR USE

It is a violation of Federal Law to use the product in a manner inconsistent with its labeling For all disinfection of hard, non-porous surfaces, stainless steel, chrome, glass and vinyl, apply with a cloth or brush or by immersing equipment to be disinfected. All hard surfaces must be wet thoroughly, and remain wet for at least 10 minutes and allowed to air dry. Gross filth and heavy soil must be removed before applying cleaning solution. Discard solution when it becomes dirty, replace with fresh solution. Ready To Use Wex-Cide is a synthetic germicidal detergent with broad spectrum kill of gram positive and gram negative microorganisms, and an excellent cleaner. **DO NOT MIX WITH OTHER CLEANERS.**

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.

***READY TO USE WEX-CIDE KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in all settings in which there is an expected likelihood of soiling of hard, non-porous 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: The 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 solution, and disinfect surface with a second application of the solution. For large spills the contaminated area should be flooded with the solution before cleaning, then decontaminated with fresh 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.

b/h