

34810-21

03/05/2010

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

MAR -5 2010

Mary Anne Auer
Wexford Labs, Inc.
325 Leffingwell Avenue
Kirkwood, MO 63122

Subject: Ready To Use Wex-Cide
EPA Registration No. 34810-21
Application Dated: December 3, 2009
Receipt Dated: December 2, 2009

Dear Ms. Auer:

The following amendment submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with conditions:

Conditions:

1. You must provide the complete nomenclature for the abbreviated *Staphylococcus* organisms simply identified as "MRSA" and "MRSE".
2. Identify "Inert Ingredients" as "Other Ingredients" in the Ingredient statement on the label.
3. The "First Section" should include the instructions to "Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment.
4. Separate the misuse statement from the directions for use.

General Comments:

A stamped copy of the accepted labeling is enclosed. Submit one copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact me at Henson.Wanda@epa.gov or call (703) 308-6345.

Sincerely,

A handwritten signature in black ink, appearing to read "Wanda Y. Henson". The signature is fluid and cursive, with a large initial "W" and a stylized "H" at the end.

Wanda Y. Henson
Acting Product Manager - Team 32
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]

ACTIVE INGREDIENTS:

ortho-Phenylphenol 0.026%

ortho-Benzyl-para-Chlorophenol 0.023%

INERT INGREDIENTS: 99.951%

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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

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

Salmonella enterica including *Staphylococcus aureus* (MRSA) and *Staphylococcus epidermidis* (MRSE), *Enterococcus faecalis* Vancomycin Resistant (VRE) **TUBERCULOCIDAL ACTIVITY:**

Mycobacterium tuberculosis in the presence of 5% serum at 20° C for 10 minutes **FUNGICIDAL ACTIVITY:** AOAC Trichophyton

mentagrophytes in the presence of 5% serum **VIRUCIDAL ACTIVITY:** *Influenza A3 [Hong Kong], Adenovirus Type 2, 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 hands 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 eye. Call a Poison Control Center or doctor for further treatment advice.

STORAGE AND DISPOSAL: Store in original container in areas inaccessible to children. Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Fill container 1/4 full with water and reclose the container. Agitate vigorously and dispose of rinsate. Repeat two more times. Wrap container and put in trash or offer for recycling if available.

Revised: 12/3/2009

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, CPR manikens.)

(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.

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Revised: 12/3/2009
secticide,
Insecticide Act as

2010-21

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