

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 20, 2005

Said I. Raziq
Director of Research
Wexford Labs, Inc.
325 Leffingwell
Kirkwood, MO 63122

Subject: Wex-Cide 128
EPA Registration Number 34810-31
Application Date: March 17, 2005
EPA Received Date: March 24, 2005

Dear Mr. Raziq:

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

Proposed Amendment

- Revised labeling

Conditions

1. Revise the Virucidal Activity Test section by including the statement "...at.....1:128" per the product's last stamped label dated, January 14, 2005.
2. Revise the First Aid Statement by including the statement "**NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed." per the product's last stamped label dated, January 14, 2005.

CONCURRENCES

SYMBOL	7510						
USERNAME	[Signature]						
DATE	6-20-05						

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit three(3) copies 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 703-308-6422.

Sincerely,



Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 C)



WEX-CIDE-128

**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.....3.40%

ortho-Benzyl-para-Chlorophenol.....3.03%

INERT INGREDIENTS:.....93.57%

100.00%

EPA REGISTRATION NO. 34810-31

**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.....1:128

(AOAC Ps. aeruginosa, S. aureus, S.choleraesuis including S.aureus [MRSA] [TNSR] [GRM] and [PR] and S. Epidermidis [MRSE], Enterococcus faecalis [VRE]).

TUBERCULOCIDAL ACTIVITY:

(AOAC M. tuberculosis) in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum (at 20° C for 10 minutes).....1:128

FUNGICIDAL TEST:

(AOAC T. Mentagrophytes) in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum at.....1:128

VIRUCIDAL ACTIVITY TEST:

(*Influenza A3[Hong Kong], Adenovirus Type 2, Herpes simplex Types 1 and 2, Vaccinia virus, Human Rotavirus, and Respiratory Syncytial virus in the presence of 400 ppm hardness and 5% serum, and HIV-1 [AIDS]) in the presence of 400 ppm hardness as Calcium Carbonate and 10% serum

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS. DANGER. 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 the concentrate. Harmful if swallowed.

FIRST AID: IF IN EYES - hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice. **IF ON SKIN OR CLOTHING** - take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice. **IF INHALED** - Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice. **IF SWALLOWED** - call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

HOT LINE NUMBER: In case of an emergency call toll free 1-800-506-1146. Have the product container or label with you when calling a poison control center or doctor or going for treatment.

Made in U.S.A

ACCEPTED
with COMMENTS
EPA Letter Dated:

JUN 20 2005

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 34810-31

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WEX-CIDE-128

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 Wex-Cide-128 at a dilution of 1 ounce per gallon of water for walls, floors, bathroom fixtures, stainless steel, chrome, glass and vinyl. Wex-Cide-128 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 and allowed to air dry. 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-128 is suitable for cleaning floors and walls in the departments of food processing plants at 1:128 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

***WEX-CIDE-128 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-128 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

WEX-CIDE-128 solution, and disinfect surface with a second application of the WEX-CIDE-128 solution. For large spills the contaminated area should be flooded with the WEX-CIDE-128 solution before cleaning, then decontaminated with fresh WEX-CIDE-128 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.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. **PESTICIDE STORAGE:** Keep upright with cap tightly closed. Store in original container in areas inaccessible to children. **PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Do not reuse empty container. Triple rinse (or equivalent), then offer for recycling or reconditioning, or dispose of in a sanitary landfill or by incineration, if allowed by state and local authorities. Consult federal, state, or local disposal authorities for approved alternate procedure. If burned, stay out of smoke.

Wexford Labs, Inc.

EPA ESTABLISHMENT NUMBER 34810-MO-1

WC-128-013105

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