



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

January 14, 2005

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

Subject: **Wex-Cide 128**  
EPA Registration No. 34810-31  
Letter Date: October 20, 2004  
Receipt Date: October 21, 2004

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 comments.

**Proposed Label Amendment**

Revise Directions for Use

**Label Comments**

1. Revise the subheading "Statement of Practical Treatment" to "**FIRST AID.**" The first aid statement must be revised to read as follows:

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.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

<b>UNITED STATES ENVIRONMENTAL PROTECTION AGENCY</b>	
<b>IF SWALLOWED</b>	<ul style="list-style-type: none"> <li>- Call a Poison Control Center or doctor immediately for treatment advice.</li> <li>- Have person sip a glass of water if able to swallow.</li> <li>- Do not induce vomiting unless told by a Poison Control Center or doctor.</li> <li>- Do not give anything by mouth to an unconscious person</li> </ul>
<b>HOT LINE NUMBER</b>	
In case of an emergency call toll free 1-800-xxx-xxxx. Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
<b>NOTE TO PHYSICIAN</b>	

2. Remove the sentence "Keep Out of Reach of Children" from the Precautionary Statements.

3. Revise and add the subheading: "Pesticide Storage" in the Storage and Disposal section:

<b>STORAGE AND DISPOSAL</b>
Do not contaminate water, food or feed by storage or disposal.
"PESTICIDE STORAGE: You must place your storage text here.
"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: Triple rinse (or equivalent). Then offer . . . If burned, stay out of smoke.

*Refer to PR Notice 83-3 for detailed information.*

**General Comments**

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

  
 Adam Heyward  
 Product Manager (34)

Regulatory Management Branch II  
 Antimicrobials Division (7510C)

SYMBOL							
SURNAME	Enclosure						
DATE							



# 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).

<b>ACTIVE INGREDIENTS:</b>	
ortho-Phenylphenol.....	3.40%
ortho-Benzyl-para-Chlorophenol.....	3.03%
<b>INERT INGREDIENTS:</b> .....	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 at..... 1:128

#### 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 the concentrate. Harmful if swallowed.

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

**NOTE TO PHYSICIANS:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. 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.

**ACCEPTED** Made in U.S.A  
with **COMMENTS**  
EPA Letter Dated:

JAN 14 2005

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

3  
8  
4

**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 pre-clean 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.

Wexford Labs, Inc.

ACCEPTED  
with COMMENTS

EPA ESTABLISHMENT NUMBER 34810-MO-1

EPA Letter Dated: WC-128-101804

JAN 14 2005

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

Handwritten marks: 4, 8, 4