

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (H7505C) 401 "M" St., S.W.

Washington, D.C. 20460

34810-31

ÉPA Reg. Number:

10/10/97

Date of Issuance. OCT 1 0 1997

Term of Issuance:

Conditional

NOTICE OF PESTICIDE:

<u>x</u> Registration _ Reregistration

Name of Pesticide Product:

WEX-CIDE 128

(under FiFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Wexford Labs, Inc.

325 Leffingwell Avenue

Kirkwood, MO 63122

AttN: Mr. Said I Raziq - Director of Research

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

- Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
- Change the label by revising the EPA Registration Number to read, "EPA Reg. No. 34810-31".
- Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

OCT 10 1997

Confidential Statement of Formula

The Confidential Statement of Formula dated August 14, 1997 is in compliance with PR Notice 91-2, and it agrees with the proposed label and is acceptable with comments.

Please submit a revised CSF and revise the lower certified limits for the active ingredient. The lower certified limit should be lower than the nominal concentration.

You <u>must</u> either submit a product chemistry data matrix for this end-use product as required in 40 CFR part 158.155-190 or indicate another EPA registered substantially similar product and place on your revised CSF under column 12.

Since the agency has reviewed your Confidential Statement of Formula dated August 14, 1997, is acceptable, no further action or comments will be necessary and the revised CSF will be placed in your agency file.

If you have further questions, please contact LaVerne Dobbins at (703) 308-6378.

Sincerely,

Portia M. Jerkins

Acting Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510W)

Enclosure:

ACCEPTED
with COMMENTS
in EPA Letter Dated:
OCT | 0 1997

Under the Federal Insecticide,
Fingicide, and Rodenticide Act as
accorded, for the posticide,
registered under EPA Reg. No. 34411 -3



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 soll (5% serum).

ACTIVE INGREDIENTS:

ortho-Phenylphenol	3.40%
ortho-Benzyl-para-Chlorophenol	
INERT INGREDIENTS:	93.57%

EPA REGISTRATION NO. 34810-8

KEEP OUT OF REACH OF CHILDREN.
DANGER

See side panel for additional precautionary statements.

Wexford Labs, Inc.

325 Leffingwell Avenue

Kirkwood, Missouri 63122

100.00%

FOR INDUSTRIAL AND INSTITUTIONAL USE Contents: One U.S. Gallon (128 Fluid Ounces) or 3.785 Liters

GERMICIDAL QUALIFICATIONS:

TUBERCULOCIDAL ACTIVITY TEST:

FUNGICIDAL TEST:

VIRUCIDAL ACTIVITY TEST:

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 it 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 wath contaminated clothing before reuse. If swallowed drink promptly a large quantity of water. Avoid alcohol and call a physician.

NOTE TO PHYSICIAN: 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 inclineration, if allowed by state and local authorities. Consult lederal, state or local disposal authorities for approved afternative procedure.

Made in U.S.A.

ACCEPTED with COMMENTS in EPA Letter Dated: 0CT | 0 1997

Finder the Federal Insecticide,
Fragminde, and Rodenticide Act as
vacculed, for the pesticide,
Fragmitered under EPA Reg. No. 34810-31

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 at a dilution of 1 ounce per gallon of water for walls, floors, bathroom fixtures, stainless steel, chrome, glass and vinyl. WEX-CIDE 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. 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 is suitable for cleaning floors and walls in all 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 sterifization or high fevel disinfection.

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