

34810-31



11/13/2008

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UNIT STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

November 13, 2008

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

Subject: **Wex-Cide 128**  
EPA Registration No. 34810-31  
Application Dated: September 23, 2008  
Receipt Date: September 24, 2008

Dear Ms. Auer:

The following amendment, submitted in connection with registration under section of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable.

**Proposed Amendment:**

- Updated labeling

**Other comments:**

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/pesticides/regulating/registering/submissions/index.htm>. If you have questions concerning electronic labeling, a list of contacts is available at the following site: <http://www.epa.gov/oppfead1/eds/edsgoals.htm#contacts>.

A stamped copy of the accepted labeling is enclosed.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-6422 or email address at: [heyward.adam@epa.gov](mailto:heyward.adam@epa.gov), or Renae Whitaker telephone at (703) 308-7003 or email address at: [whitaker.renae@epa.gov](mailto:whitaker.renae@epa.gov) during the hours of 8:00 am to 3:30 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,



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

Enclosure: EPA stamped approved labeling

# [Wex-Cide 128]

[CONCENTRATED GERMICIDAL DETERGENT]  
[ONE-STEP DISINFECTANT]

[Whirlpool Pedicure Spa One-Step Disinfectant  
Concentrated One-Step Germicidal Detergent]

**CLEANS • DISINFECTS • DEODORIZES**

GERMICIDAL, PSEUDOMONACIDAL, TUBERCULOCIDAL, FUNGICIDAL and  
VIRUCIDAL\*

[For use in Whirlpool baths, Foot Spas, Beauty Salons, Barber shops and  
Hospitals]

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%

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

See side panel for additional precautionary statements

#### [Wex-Cide 128]

- [Is to clean and disinfect washable hard nonporous surfaces of: whirlpool baths, foot spas, salon/barber tools and instruments: combs, brushes, and manicure instruments.]
- [Meets AOAC efficacy standards for hospital disinfectants.]
- [Is a proven "one-step" disinfectant - cleaner - fungicide - tuberculocide - virucide\* which is effective in soft or hard water up to 400 ppm hardness in the presence of organic soil (5% serum).]

[PREPARATION OF DISINFECTANT USE-SOLUTION: ADD (MIX) 1 OZ. PER GALLON OF WATER]

**Wexford Labs, Inc.**

325 Leffingwell Avenue  
Kirkwood, Missouri 63122



EPA Reg. No. 34810-31

EPA Est. No. [Insert Est. No. here]

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

Note to reviewer: Language in [ ] is optional or interchangeable

#### GERMICIDAL OR [BACTERIACIDAL] 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. enterica including S. aureus [MRSA] [NSR] [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

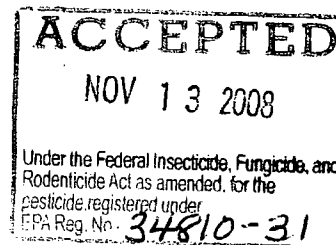
#### PRECAUTIONARY STATEMENTS

**HAZARD TO HUMANS AND DOMESTIC ANIMALS. DANGER.** 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. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

Made in U.S.A.



**[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 this product at a dilution of 1 ounce per gallon of water for walls, floors, bathroom fixtures, stainless steel, chrome, glass and vinyl.

**[AREAS OF USE:]**

[Hospitals]	[Schools]
[Health Care Facilities]	[Bathrooms]
[Medical Offices]	[Whirlpool (baths) (units)]
[Dental offices]	[Turkey farms]
[Day care centers]	[Poultry farms]
[Nurseries]	[Zoos]
[Nursing homes]	[Foot spas]
[Institutions]	[Salons (Beauty)]
[Institutional facilities]	[Whirlpool pedicure spa]
[Barber Shops]	

**[TYPES OF SURFACES:]**

[On washable hard, nonporous surfaces of:]  
[Bathroom fixtures]  
[Floors]  
[Walls]  
[Stainless Steel]  
[Chrome]  
[Glass]  
[Vinyl]

**[FARM PREMISE, LIVESTOCK, POULTRY & TURKEY HOUSE DISINFECTANT]**

**[DILUTION:** 1:128 1 oz. per gallon of water

1. Remove all animals and feeds from premises, trucks, coops, crates, and enclosures.
2. Remove all litter and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, vehicles, and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent, and rinse with water.
5. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.
7. Ventilate buildings, coops, cars, trucks, boats, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried.
8. After treatment with disinfectant, thoroughly scrub feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.]

[This product at 1 oz. per gallon of water (1:128) is suited for disinfecting and cleaning in poultry and turkey barns, breeder and laying operations.]

[Poultry house grow-out operations and hatcheries: Use in hatchers and setters, evaporative coolers, humidifying systems and ceiling fans, live haul equipment, chick busses, transfer trucks, trays, coop washing, polyethylene chick boxes, foot pans and feed bins.]

[Equine facilities: Use in stables, stalls, breeding and foaling areas and transport vehicles.]

**[SALON/BARBER INSTRUMENTS AND TOOLS DISINFECTION BACTERICIDE / VIRUCIDE/ FUNGICIDE DIRECTIONS:**

Mix 1 oz. (30 mL) of [this product] per gallon of water (0.25 oz (7.5 mL) of this product per quart of water) to disinfect hard, nonporous instruments and tools. Completely immerse combs, brushes, rollers, manicure and other salon instruments and tools for 10 minutes. For heavily soiled instruments and tools, a preliminary cleaning is required. Rinse thoroughly and dry before use. Fresh solution should be prepared daily or more often if solution becomes diluted or soiled.

**Note:** Plastics may remain immersed until ready to use. Stainless steel instruments must be removed after 10 minutes, rinsed, dried, and kept in a clean non-contaminated receptacle. Prolonged soaking may cause damage to metal instruments.]

[This product's] 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. [This product] is suitable for cleaning floors and walls in the departments of food processing plants at 1:128 use dilution.

**[DISINFECTION OF WHIRLPOOL (BATH(S) (UNITS) FOOT SPAS:**

After using the [whirlpool (bath) (unit), (foot spa), drain and refill with fresh water to (just cover the intake valve) (cover the highest jet) (2 inches above the highest jet). Add 1 ounce of [this product] for each gallon of fresh water added. Start the pump to circulate the solution. Wash down [the (deck) (seat of chair life) (any related equipment)] any uncovered surfaces on the (bath) (unit) (foot spa) with a clean swab, brush or sponge with the solution. Treated surfaces must remain wet for 10 minutes. After the (bath) (unit) (foot spa) has been thoroughly disinfected, drain and rinse surfaces with fresh water. Wipe dry with a clean sponge or cloth or allow to air dry. Repeat for heavily soiled units.]

**\*[THIS PRODUCT] 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:** [THIS PRODUCT] 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 [THIS PRODUCT] solution, and disinfect surface with a second application of the [THIS PRODUCT] solution. For large spills the contaminated area should be flooded with the [THIS PRODUCT] solution before cleaning, then decontaminated with fresh [THIS PRODUCT] 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.

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[Packaged by:]  
[Lighthouse for the Blind]  
[St. Louis, MO 63132-1209]  
[800-542-3697]

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