



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

JUL 22 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

Subject: Wex-cide Concentrated Germicidal Detergent
EPA Registration No.: 34810-8
Application Date: 06/15/2011
Receipt Date: 06/17/2011

Dear Ms. Auer:

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable with conditions.

Proposed Amendment

- Deletion of efficacy claims against *S. aureus*, *Ps. aeruginosa*, *S. enterica*, and *M. bovis* in the presence of 5% blood serum
- Revised Precautionary statements, Special Instructions, and Storage & Disposal statements
- Addition of use sites and areas with corresponding directions and optional marketing language
- Deletion of the uncommon abbreviations for antibiotic resistant organisms: TNSR, GMR, and PR
- Addition of Pandemic H1N1 claim

Conditions

Revise the label as follows:

- 1) Correct the Precautionary Statements to read:

"Corrosive. Causes irreversible eye damage. May be fatal if absorbed through skin. Harmful if inhaled or swallowed. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse."

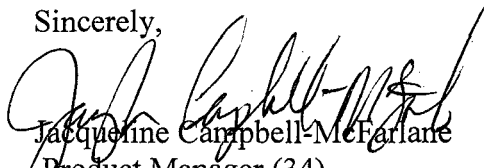
- 2) Place the First Aid statements in a text box for prominence and separate this from the Precautionary Statements.
- 3) Delete the term "recommended" on in the fifth bullet under the Farm Premise, Livestock, Poultry & Turkey House Disinfectant directions on page 2.
- 4) Since this product does not support blood serum efficacy data, all directions must indicate to "pre-clean surfaces prior to disinfection."
- 5) Delete "or" under the Personal Protection for HIV-1 because the PPE is not optional when cleaning blood spills.

General Comments

A stamped label with conditions is enclosed for your records. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at Campbell-mcfarlane.jacqueline@epa.gov or Jaclyn Carl by telephone at (703) 347-0213 or by e-mail at carl.jaclyn@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,


Jacqueline Campbell-McFarlane
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

[Wex-Cide]

[CONCENTRATED GERMICIDAL DETERGENT]

[Whirlpool Pedicure Spa Disinfectant]

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)

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]

- [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 disinfectant – cleaner – fungicide – tuberculocide – virucide* which is effective in soft or hard water up to 400 ppm]

[PREPARATION OF DISINFECTANT USE-SOLUTION: ADD (MIX) 1/2 OZ. PER GALLON OF WATER]

Wexford Labs, Inc.
325 Leffingwell Avenue
Kirkwood, Missouri 63122



EPA Reg. No. 34810-8

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

FOR INDUSTRIAL AND INSTITUTIONAL USE

Contents: One U.S. Gallon (128 Fluid Ounces) or 3.785 Liters

GERMICIDAL OR [BACTERIACIDAL] QUALIFICATIONS:

(AOAC Use Dilution Confirmation) in the presence of 400 ppm hardness as Calcium Carbonate 1:256

(AOAC Ps. aeruginosa, S. aureus, S. enterica including methicillin resistant S. aureus [MRSA] and S. Epidermidis [MRSE], Enterococcus faecalis [VRE]).

TUBERCULOCIDAL ACTIVITY:

(AOAC M. tuberculosis) in the presence of 400 ppm hardness as Calcium Carbonate 5% (at 20° C for 10 minutes) 1:256

FUNGICIDAL TEST:

(AOAC T. Mentagrophytes) in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum at..... 1:256

VIRUCIDAL ACTIVITY TEST:

(*Influenza A3 virus [Hong Kong], Pandemic 2009 H1N1 Influenza A Virus (formerly called Swine Flu), Adenovirus Type 2, Herpes simplex virus 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..... 1:256

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) 424-9300. 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.

**ACCEPTED
with COMMENTS**

EPA Letter Dated:

JUL 22 2011

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
as registered under EPA Reg. No.
34810-8

[Wex-Cide]
[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 1/2 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]

Surface Cleaning: Prior to surface disinfection, pre-clean surfaces, making sure to remove all gross filth and heavy soil, by saturating surfaces with [this product] use solution and allowing surfaces to remain wet for 15 seconds; then wipe clean.

[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 1:256 use dilution.

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

[DILUTION: 1:256 1/2 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 1/2 oz. per gallon of water (1:256) 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 1/2 oz. (15 ml) of [this product] per gallon of water or 0.125 oz. (3.75 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.]

[WHIRLPOOL FOOT SPA DISINFECTION: After using whirlpool foot spa, drain the water. Use 1/2 oz. of [this product] per gallon of water to cover intake valve. Start pump to circulate the solution. Swab exposed surfaces including unit sides, chairs, and any related equipment thoroughly with cloth, sponge, or brush and allow treated surfaces and solution to stand for 10 minutes. After unit has been thoroughly disinfected, rinse all disinfected surfaces with fresh water.]

[DISINFECTION OF [WHIRLPOOL (BATH(S) (UNITS))]:


After using the [whirlpool (bath) (unit)], drain and refill with fresh water to (just cover the intake valve) (cover the highest jet) (2 inches above the highest jet). Add ½ 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) (any related equipment)] any uncovered surfaces on the (bath) (unit) with a clean swab, brush or sponge with the solution. Treated surfaces must remain wet for 10 minutes. After the (bath) (unit) 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.]

DECONTAMINATION OF CRITICAL OR SEMI-CRITICAL DEVICES PRIOR TO TERMINAL STERILIZATIONS/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.

***[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  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 HANDLING: Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available, or puncture and dispose of in a sanitary landfill or by incineration. Do not burn unless allowed by state and local ordinances.

062011

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

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