

34810-31

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

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OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENT

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

Subject: **Wex-Cide 128**
EPA Registration No. 34810-31
Application Date: September 28, 2012
Receipt Date: August 30, 2012

Dear Ms. Auer:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3 (c) 7 A as amended, is acceptable.

Proposed Amendment:

- Adding Additional Organisms: Acinetobacter baumannii and Rhinovirus (type 37)

Data Summary

Data Requirement	Means of Support	Status
Pseudomonas aeruginosa	Submitted study, MRID 489245-01,	Acceptable, RTU @ 10 minutes
Acinetobacter baumannii	Submitted study, MRID 489245-02	Acceptable, RTU @ 10 minutes
Feline Calicivirus	Submitted study, MRID 489245-03	Unacceptable RTU @ 10 minutes
Avian Influenza Virus (H9N2) & (H5N1)	Submitted study, MRID 489245-04	Acceptable, RTU @ 10 minutes
Rabies Virus	Submitted study, MRID 489245-05	Unacceptable
Rhinovirus type 37	Submitted study, MRID 489245-06	Acceptable in 5% soil

Label Comments:

- 1. The second statement under Precautionary Statements must be revised to read: "Causes irreversible eye damage."
- 2. Add the following statement to the Precautionary Statements:

"wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse."
- 3. PRN 2005-1, Guidance for Mandatory and Advisory Labeling Statements, states that:
Mandatory statements, which commonly use imperative verbs such as "must" or "shall", either require action or prohibit the user from taking certain action. **Advisory statements** generally provide information, either in support of the mandatory statements or about the product in general. **To ensure that the intent of each labeling statement is clear, mandatory statements need to be clearly distinguishable from advisory statements.**

Therefore, you must revise step 5 under Farm Premise, Livestock section on page 2 by deleting the term, "recommended" to "requirement" or such that it is in compliance with PRN 2005-1.

General Comments

A stamped label is enclosed for your records. Submit (1) one final printed label bearing the revised labeling prior to selling or distributing the product.

Should you have any questions concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by email at grigsby.stacey@epa.gov during the hours of 8:00 am to 4:00 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,



Jacqueline McEarlane
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

[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]

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 - virucide - virucide*]

[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

GERMICIDAL OR [BACTERIACIDAL] QUALIFICATIONS:

Pseudomonas aeruginosa [Ps. aeruginosa] Staphylococcus aureus [S. aureus],
Salmonella enterica [S. enterica] including Methicillin resistant Staphylococcus aureus
[MRSA] and Methicillin resistant Staphylococcus epidermidis [MRSE], Enterococcus
faecalis [VRE], Acinetobacter baumannii in 400 ppm hard water and 5% serum at... 1:128

TUBERCULOCIDAL ACTIVITY:

(AOAC M. bovis) in the presence of 400 ppm hard water (at 20° C for 10 minutes) on
previously cleaned hard non-porous surfaces 1:128

FUNGICIDAL TEST:

(AOAC T. Mentagrophytes) in the presence of 400 ppm hard water and 5% serum at 1:128

VIRUCIDAL ACTIVITY TEST:

Influenza A3 [Hong Kong], Pandemic 2009 H1N1 Influenza A Virus (formerly called
Swine Flu), Adenovirus Type 2, Herpes simplex Types 1 and 2, Vaccinia virus, Human
Rotavirus, and Respiratory Syncytial virus, Rhinovirus (type 37) in the presence of 400
ppm hard water and 5% serum..... 1:128
HIV-1 [AIDS] in the presence of 400 ppm hard water and 10% serum at 1:128
Feline Calicivirus (surrogate for Norovirus) in the presence of 400 ppm hard water
previously cleaned hard non-porous surfaces 1:128
[Avian Influenza Virus (H9N2) (Charles River Laboratories) (H5N1)(NIBRG-14) in the
presence of 400 ppm hardness and 5% 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

against circulatory shock, respiratory depre:

ACCEPTED

with COMMENTS

EPA Letter Dated:

JAN 17 2013

Made in U.S.A

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

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

[Wex-Cide 128]
[CONCENTRATED GERMICIDAL DETI

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

[TYPES OF SURFACES:]

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

[This product's] solution may be applied with a cloth, mop or brush, or by soaking

For heavily soiled surfaces, pre-clean according to General Cleaning Directions

For use as a Cleaner and/or Deodorizer: Apply use solution evenly over surface to be cleaned. Wipe with clean cloth, mop, sponge or paper towel.

To Disinfect: Wet all surfaces thoroughly. Let stand for 10 minute contact time before wiping or rinsing, or allow 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 must 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.

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

[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] ^{live} 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. ^{a person slip a glass}
7. Ventilate buildings, coops, cars, trucks, boats, and other ^{released} 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 must 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.

a person slip a glass
in the released soap
FOOT SPAS
has been

[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.]

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 and 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 must 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 must be autoclaved and disposed of according to Federal, State and local regulations for infectious waste disposal.

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

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.

For Non-refillable sealed containers Note to reviewer: This packaging option is a sealed container designed to reduce worker exposure to concentrate. It cannot be opened or triple rinsed.

CONTAINER DISPOSAL: Nonrefillable container. Do not refill or reuse this container. Wrap empty container and put in trash.

[Packaged by:]

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

[Produced with Pride by Americans Who are Blind.]
[Skilcraft is a registered trademark, licensed by National Industries for the Blind]

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