

34810-31

12/20/2011

1046



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

DEC 20 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

Subject: Wex-Cide 128
EPA Registration No.: 34810-31
Notification Date: 11/30/2011
EPA Receipt Date: 12/01/2011

Dear Ms. Auer,

This letter acknowledges receipt of your notification submitted under the provision of FIFRA section 3(c)9 and PR Notice 98-10.

Proposed Notification

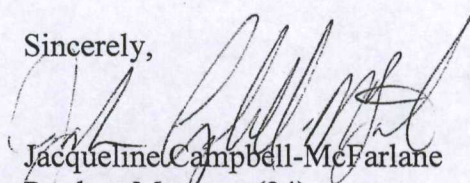
- Removal of 5% blood serum claim for Tuberculocidal efficacy
- Addition of H1N1 claim

General Comments

Based on a review of the submitted materials, your notification for the label revisions in response to Agency letter dated 07/22/11 is acceptable and has been made a part of your file.

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)

2096

Please read instructions on reverse before completing form.

Form Approved OMB No. 2070-0060



United States
Environmental Protection Agency
Washington, DC 20460

<input type="checkbox"/>	Registration
<input checked="" type="checkbox"/>	Amendment
<input type="checkbox"/>	Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 34810-31	2. EPA Product Manager Jacqueline McFarlane	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Wex-Cide 128	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Wexford Labs, Inc. 325 Leffingwell Avenue Kirkwood, MO 63122 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
 Remove claim of TB efficacy in 5% blood serum.
 Add H1N1 Claim
 This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. 2055 grams No. per container 6	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt _____ No. per container _____	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
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*** Certification must be submitted**

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 12" H x 5.75" W	5. Location of Label Directions <input type="checkbox"/> On the bottle
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other Silk Screened on the bottle

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name Mary Anne Auer	Title CEO	Telephone No. (include Area Code) 314-966-4134
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Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title CEO	6. Date Application Received (Stamped)
4. Typed Name Mary Anne Auer	5. Date 11/29/2011	

Wexford Labs

Disinfectant Solutions

November 30, 2011

Ms. Jacqueline McFarlane
(Acting) Product Manager (34)
Regulatory Management Branch II
United States Environmental Protection Agency
Antimicrobial Division (7510P)
2777 Crystal Drive
Potomac Yard 1
Arlington, VA 22202

Re: 34810-31 Wex-Cide 128 Notification

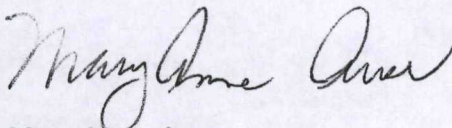
Dear Ms. McFarlane:

I have enclosed the following:

- Form 8570-1 Notification for Wex-Cide 128 (EPA # 34810-31)
 - o Removal of 5% blood serum claim for Tuberculocidal efficacy
 - o Addition of H1N1 Claim
- Three copies of our Wex-Cide 128 (EPA # 34810-31) updated label

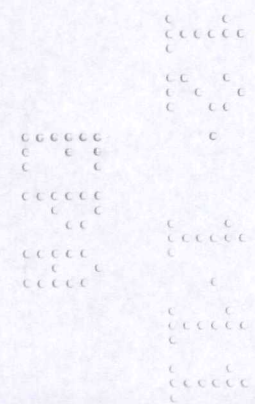
I appreciate your assistance with this process.

Sincerely,
WEXFORD LABS, INC.



Mary Anne Auer
CEO

Enclosures



[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*]

[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] and Enterococcus
faecalis [VRE] in the presence of 400 ppm hardness as Calcium Carbonate and 5%
serum at..... 1:128

TUBERCULOCIDAL ACTIVITY:

(AOAC M. bovis) in the presence of 400 ppm hardness as Calcium Carbonate (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 hardness as Calcium Carbonate
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 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

NOTIFICATION
Data Reviewed: G. Lead
Reviewed By: H. H. 7/20/11

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

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[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 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]
- [Nurseries]
- [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 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.

For use as a One-Step Cleaner/Disinfectant: 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 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 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 buses, 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.]

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2

[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.]

[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 pre-clean 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.

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.

11/29/11

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

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

6096