

34810-16

06-13-2011

1/5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

JUN 13 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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

Subject: Phenex-Cel
EPA Registration Number: 34810-16
Amendment Date: December 1, 2010
EPA Receipt Date: December 3, 2010

Dear Ms. Auer:

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

Proposed Amendment:

- Amending the registration to add claims against Methicillin-resistant Staphylococcus aureus, Vancomycin-resistant Enterococcus faecalis, and Pandemic 2009 H1N1 Influenza virus.

Conditions

Revise label as follows:

1. The nomenclature for Influenza A₃ [Hong Kong] and Herpes Simplex Type 2 is incomplete. You need to add the term, "virus," such that it reads "Influenza A₃ Virus [Hong Kong] and Herpes Simplex Virus Type 2."
2. The "Precautionary Statements" need to be updated to be in agreement with the Label Review Manual and this product's acute toxicity profile by stating:

Corrosive. Causes irreversible eye damage. Harmful if absorbed through the skin. Do not contact eyes, skin, or clothing. Wear goggles or faceshield and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, smoking tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

3. Revise the last statement in the 1st paragraph under the "Directions for Use" heading and "Salon/Barber Instruments and Tools" directions to be in compliance with PR Notice 2000-5,

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Mandatory Labeling by deleting the term, should, and stating "must."

4. Revise the 5th instruction under "Farm Premise/Livestock/Poultry & Turkey House Disinfectant" directions to bring it in compliance with PR Notice 2000-5 by deleting the term "recommended" and stating "1 oz per gallon of water."

Data Summary


Data Requirement	Means of Support	Status
Staphylococcus aureus MRSA	Submitted study, MRID 483649-01	Acceptable, 1 oz/gallon of water @ 10 min in 400 ppm hard water and 5% serum
Enterobacter aerogenes-VRE	Submitted study, MRID 483649-02	Acceptable, 1 oz/gallon of water @ 10 min in 400 ppm hard water and 5% serum

General Comments

A stamped label with conditions is enclosed for your records. Submit one (1) copy of the final printed label before distributing or selling the product bearing the revised labeling.

If you have questions concerning this letter, then please contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Killian Swift by telephone at (703) 308-6346 email address at swift.killian@epa.gov. When you are submitting information or data in response to this letter, send a copy of this letter to accompany the submission in order to facilitate processing.

Sincerely,



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

Enclosure: EPA stamped label
 Efficacy Data Evaluation

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

[PHENEX-CEL]
[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, sodium salt..... 8.45%

ortho-Benzyl-para-Chlorophenol, sodium salt..... 7.15%

INERT INGREDIENTS:..... 84.40%

100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER

See side panel for additional precautionary statements

[Phenex-Cel]

- [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. 34810-16

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
 Phenex-Cel Label

GERMICIDAL OR [BACTERIACIDAL] QUALIFICATIONS:

(AOAC Use Dilution Confirmation) in the presence of 400 ppm hardness as Calcium Carbonate and 5% serum at.....1:128

Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella enterica including Methicillin-resistant Staphylococcus aureus (MRSA) and Enterococcus faecalis Vancomycin Resistant (VRE)

TUBERCULOCIDAL ACTIVITY:

Effective against Mycobacterium bovis [OT# 451C150] in 10 minutes at 21°C / 70°F 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], kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu), Herpes simplex Type 2, Vaccinia 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. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash clothing before reuse.

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 SWALLOWED: Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the Poison Control Center or doctor. Call a Poison Control Center or doctor immediately for treatment advice. In case of emergency call Chemtrec at 800-424-9300. Have the product container or label with you when calling a Poison Control Center or doctor.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed. (Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment).

ACCEPTED
 with COMMENTS
 EPA
 JUN 13 2011

Made in U.S.A.

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

34810-16

Handwritten signature

**[Phenex-Cel]
[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, nonporous surfaces in hospitals, health care facilities, schools, and nursing homes, such as floors, walls, bathroom fixtures, shower room stalls, use [this product] at 1 ounce per gallon of water. [This product's] use solution may be applied with a cloth, mop or brush, or by immersing equipment to be disinfected. Wet all surfaces thoroughly. Let solution remain on surface for a minimum of 10 minutes. Rinse or allow to air dry. [This product's] use solution may be used on surfaces such as stainless steel, chrome, glass, vinyl, glazed ceramic, and terrazzo. 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.

[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]
[Glazed Ceramic]
[Terrazzo]

[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.]

[WHIRLPOOL FOOT SPA DISINFECTION: After using whirlpool foot spa, drain the water. Use 1 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 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) (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 HUMAN IMMUNODIFICIENCY VIRUS TYPE 1 (HIV) ON PRECLEANED, 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 minutes with a solution of 1 oz per gallon of water. This contact time will not control other common types of viruses and bacteria listed on the label.

Cleaning Procedure: [This product] use 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's] solution, and disinfect surface with a second application of the [this product's] solution. For large spills the contaminated area should be flooded with the [this product's] solution before cleaning, then decontaminated with fresh [this product's] solution.

DISPOSAL OF INFECTIOUS MATERIAL: Blood, body fluids, cleaning materials and clothing 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 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.

011811

5/14