



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 10, 2019

Catherine Kickham
Director of Strategic Development
Wexford Labs, Inc.
325 Leffingwell Ave.
Kirkwood, MO 63122

Subject: PRIA Label Amendment – Add Additional Organisms and Claims to the Master Label
Product Name: PHENEX-CEL
EPA Registration Number: 34810-16
Application Date: Oct. 1, 2018
Decision Number: 546193

Dear Ms. Kickham:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

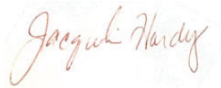
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Srinivas Gowda by phone at (703) 308-6354 or via e-mail at gowda.srinivas@epa.gov

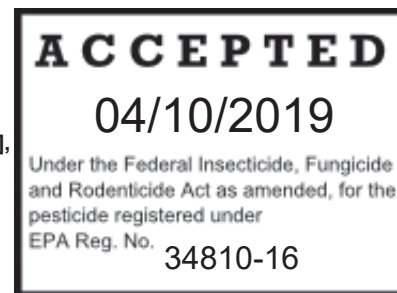
Sincerely,



Jacqueline Hardy
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division

Enclosure: EPA Stamped Label

[PHENEX-CEL]
[CONCENTRATED GERMICIDAL DETERGENT]
[ONE-STEP DISINFECTANT]
[CLEANS] • [DISINFECTS] • [DEODORIZES]
[GERMICIDAL], [PSEUDOMONACIDAL], [TUBERCULOCIDAL],**
[FUNGICIDAL] and [VIRUCIDAL*]



ACTIVE INGREDIENTS:	
ortho-Phenylphenol, sodium salt	8.45%
ortho-Benzyl-para-Chlorophenol, sodium salt.....	7.15%
INERT INGREDIENTS:	<u>84.40%</u>
.....	100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER

See [right] [left] [side] [back] panel for Precautionary Statements and First Aid

[This product]

- [Is to clean and disinfect washable hard nonporous surfaces of: whirlpool baths, foot spas, salon/barber tools and instruments: combs, brushes, and manicure instruments.]
- [Proven Effective as a One-Step Cleaner-Disinfectant in the Presence of 5% Organic Serum for Poultry, Swine, Animal Care Facilities, Livestock and Veterinary Uses.]
- [Tested according to AOAC Use-Dilution Method.]
- [Is a proven “one-step” disinfectant – cleaner – fungicide – virucide* which is effective in soft or hard water up to 400 ppm hardness in the presence of organic soil (5% serum).]

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

Efficacy Claims

[BACTERIA]:

[In the presence of 5% blood serum] and [in 400 ppm hard water,] contact time 10 minutes is effective against:

Dilution: 1:128 1 oz per gallon of water

{or}

[Dilution: 1 oz.] per gallon of water]

Enterobacter aerogenes
Enterococcus faecalis Vancomycin Resistant (VRE)
Escherichia coli O157:H7
Klebsiella pneumoniae
Methicillin-resistant Staphylococcus aureus (MRSA)
Pseudomonas aeruginosa
Salmonella enterica
Staphylococcus aureus

Dilution: 1:256 ½ oz per gallon of water

{or}

[Dilution: ½ oz.] per gallon of water]

Salmonella enterica

*Virus

** Pseudomonas aeruginosa

[FUNGICIDAL:]

[In the presence of 5% blood serum] and [in 400 ppm hard water,] contact time 10 minutes is effective against:

Dilution: 1:128 1 oz per gallon of water

{or}

[Dilution: 1 oz.] per gallon of water]

Trichophyton interdigitale

[TUBERCULOCIDAL:]

[In the presence of 5% blood serum at 20° C] and [in 400 ppm hard water,] contact time 10 minutes is effective against:

Dilution: 1:128 1 oz per gallon of water

{or}

[Dilution: 1 oz.] per gallon of water]

Mycobacterium bovis [OT# 451C150]

[VIRUCIDAL*:]

[In the presence of 10% blood serum] and [in 400 ppm hard water,] contact time 10 minutes is effective against:

Influenza A3 Virus [Hong Kong] [kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu)]

Herpes Simplex Virus Type 2

HIV-1 [AIDS]

Vaccinia virus

[ANIMAL VIRUSES*:]

[In the presence of 5% blood serum] and [in 400 ppm hard water,] contact time 10 minutes is effective against:

Dilution: 1:128 1 ounce per gallon of water

{or}

[Dilution: 1 oz.] per gallon of water]

Porcine Epidemic Diarrhea Virus (PEDV)

Dilution: 1:256 ½ ounce per gallon of water

{or}

[Dilution: ½ oz.] per gallon of water]

Avian Influenza A (H5N1)

Newcastle Disease Vr-109

Porcine Respiratory and Reproductive Syndrome (PRRS)

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS. DANGER. Corrosive. Causes irreversible eye damage. Harmful if absorbed through the skin. Avoid breathing spray mist. Do not contact eyes, skin, or clothing. Wear goggles or faceshield and rubber gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, smoking 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)*

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 wet on surface for a minimum of 10 minutes. Reapply as necessary. 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. Visible 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.

[AREAS OF USE:]

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

[TYPES OF SURFACES:]

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

[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 visibly 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.]

[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.]

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

[DILUTION: 1:256 ½ 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 ½ oz. per gallon of water 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 ½ oz. per gallon of water (1:256) is suited for disinfecting and cleaning in poultry and turkey barns, breeder and laying operations.]

†Only applies to the following organisms: Avian Influenza A (H5N1), Newcastle Disease Vr-109, Porcine Respiratory and Reproductive Syndrome (PRRS)

OR

[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 1 oz. per gallon of water 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 hatcher 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.]

[VEAL, CALVING, HOG, CATTLE AND HORSE OPERATIONS: Between depopulations of facilities, cleaning and disinfection of pens, hutches, aisles, ventilation equipment, utensils and other environmental surfaces may be required. Flush soils from these areas and clean and disinfect with ½ ounce per gallon (4 ml / liter) of [this product]. Take care to avoid spray and other contact with animals, feed or feed equipment or in water or watering devices. If spray is used on or contacts feeders or waterers, scrub them and rinse well with potable water before they are reused.

FARM BOOT BATH: Use one half (½) ounce per gallon (4 ml / liter) in farm boot baths. Change solution daily and anytime it becomes visibly soiled. Use a nylon brush to clean soils from boots.]

Where medical devices are listed as applicable sites, the following will be included as required by PR 94-4

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.

The following special instructions must be included on the label if the product is used as a hospital-grade disinfectant rather than retail/household

[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 virus).

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 when performing manual cleaning of these surfaces.

CONTACT TIME: Leave surfaces wet for 10 minutes.

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 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.

Updated 3/25/2019