

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

May 24, 2018

Michael Rekhelman ABC Compounding Co., Inc. P.O. Box 80729 Conyers, GA 30013

Subject: PRIA Label Amendment – Add Additional Organisms and Claims to the Master Label Product Name: TEK TROL II EPA Registration Number: 3862-193 Application Date: January 2, 2018 Decision Number: 537234

Dear Mr. Rekhelman:

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. Please also note that the record for this product currently contains the following CSFs:

• Basic CSF dated 05/11/2018

If you have any questions, please contact Srinivas Gowda by phone at (703) 308-6354 or via email at <u>gowda.srinivas@epa.gov</u>

Sincerely,

Jacque Hardy

Jacqueline Hardy Product Manager 34 Regulatory Management Branch II Antimicrobials Division

Enclosure: EPA Stamped Label

Tek Trol II

$\textbf{DISINFECTANT} \cdot \textbf{CLEANER} \cdot \textbf{CONCENTRATE}$

*VIRUCIDAL, BACTERICIDAL, TUBERCULOCIDAL, FUNGICIDAL

ACTIVE INGREDIENTS:

ortho-Benzyl-para-chlorophenol	13.2%
ortho-Phenylphenol	
INERT INGREDIENTS:	62.0%
TOTAL:	.100.00%

ACCEPTED 05/24/2018

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2000 100

3862-193

DANGER Keep out of Reach of Children PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CORROSIVE. Causes irreversible eye damage. Causes skin burns. Harmful if swallowed or absorbed through skin or inhaled. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor or spray mist. Wear protective eyewear such as goggles, face shield or safety glasses. Wear coveralls worn over long-sleeved shirt and long pants, socks and chemical-resistant boots, and waterproof gloves (Barrier Laminate, or Butyl Rubber, or Nitrile Rubber, or Neoprene Rubber, or Natural Rubber, or Polyethylene, or Polyvinyl Chloride (PVC), or Viton, selection category A). 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.

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 eye. Call a poison control center or doctor for treatment advice.

If on skin or on clothing: Take off contaminated clothing. Immediately rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If swallowed: Call 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 to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

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. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact 1-800-222-1222, the poison control center, for emergency medical treatment information. **NOTE TO PHYSICIAN:** Probable mucosal damage may contraindicate the use of gastric lavage.

PHYSICAL AND CHEMICAL HAZARDS

Do not apply this product in or on electrical equipment due to the possibility of shock hazard.

EPA REG. NO. 3862-193 Manufactured by: ABC Compounding Co., Inc. P.O. Box 16247 Atlanta, GA 30321-0247 Toll Free 800-795-9222 EPA EST. NO. 3862-GA-1 Net Contents:

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Handlers must wear:

- · Coveralls over long-sleeved shirt and long pants
- · Socks and chemical-resistant shoes
- · Goggles or face shield

 Chemical-resistant gloves (such as barrier laminate, butyl rubber, nitrile rubber, neoprene, rubber and viton) In addition, applicators and other handlers exposed to vapors, mist, or unexpected splash back must wait until mist has dissipated and the enclosed area has been thoroughly ventilated, or if needed, wear a full face dust/mist filtering respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R, P, or HE prefilter. Follow manufacturers instructions for cleaning/maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this products concentrate. Do not reuse them. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- · Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- · Remove personal protective equipment immediately after handling this product.
- Wash outside of gloves before removing. As soon as possible, wash thoroughly.

General Information:

This product provides effective cleaning and disinfecting in one-step, non-flammable and non-volatile in use dilutions, excellent solubility, dilutes in soft or hard water of up to 400 ppm water hardness.

The high foaming detergent system of this product has been especially formulated to provide heavy duty cleaning, wetting and penetration of soils and organic matter and easy rinsing of surfaces. Excellent clinging foam is obtained at end-use dilution to provide prolonged contact time. This product is recommended for use when used as directed on ceramic and glazed tile surfaces, stainless steel, aluminum, chrome, galvanized metal, glass, and other hard non-porous environmental surfaces such as sealed wood, polyethylene, polypropylene, PVC (polyvinyl chloride), polystyrene, vinyl, fiberglass, viton, ethylene propylene, nitrile, acrylic, and polyurethane. When used as directed, this product is suited for disinfecting and cleaning hard nonporous environmental surfaces in all areas of: swine producing facilities, including farrowing and nursery units, finishing floors, grow barns, confinement units, and transport vehicles; poultry, turkey, duck, ratite, and avian rearing facilities, including grow-out breeder barns, laying operations, and hatcheries, including hatchers and setters, evaporative coolers, fogging systems, humidifying systems, live haul equipment, chick busses, transfer trucks, coop washing, chick boxes, foot pans, trays, feed bins and buggies; calving facilities, including calf hutches and pens, freshening pens, and birthing pens; equine facilities including stables, stalls, breeding and foaling sheds and transport vehicles; hospitals, medical research centers, health care facilities, schools, animal care facilities and research centers, laboratories, veterinary clinics, zoos, and kennels. This product can also be used as a wall and floor cleaner in poultry and meat processing plants, meat packing plants, frozen food and canning operations.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product may be applied only by the methods specified on the labeling.

[Use one of the following two statements below]:

This product is not for use on critical or semi-critical medical device surfaces. *[or]*

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.

General Precautions and Restrictions: Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. Following application as a low pressure or high pressure spray, do not enter or allow others to enter the treated area until sprays have dried.

Solution Preparation Directions: To prepare end-use solution, dilute as directed and mix for 5 minutes or until solution is uniform.

General Use Directions: 1. To clean, disinfect and deodorize walls, floors, tables, drinking fountains, sinks, refrigerators, stoves, restroom fixtures, garbage cans and other hard non-porous environmental surfaces: Remove gross filth and heavy soil with a preliminary cleaning step prior to application of this product. Apply the end-use solution with a sponge, mop, mechanical spray device or foaming apparatus making sure that all surfaces are wetted thoroughly. Allow surface to remain wet for 10 minutes. Air dry. **2.** To clean and disinfect hard, non-porous articles such as animal food and water bowls, non-porous bird toys, non-porous perches and rubber goods: all articles must be thoroughly cleaned to remove excess debris, rinsed and rough dried, including the hollows and lumens, before immersion in solution. Soak for 10 minutes. Rinse food and water bowls prior to reuse. **3.** To clean gross filth or heavy soil on environmental surfaces prior to disinfection, use ½ - 1 oz. of this product per gallon of water.

WHEN USED AS DIRECTED, THIS PRODUCT IS EFFECTIVE AGAINST THE LISTED ORGANISMS IN WATER UP TO 400 PPM HARDNESS (AS CaCO3) IN THE PRESENCE OF ORGANIC SOIL (5% BLOOD SERUM) WITH 10 MINUTES CONTACT TIME:

BACTERICIDAL ACTIVITY - When diluted at the rate of 1/2 ounces per gallon (1 part product to 255 parts water, or 4 ml product per 1000 ml of water), this product exhibits effective, one-step disinfectant activity against Staphylococcus aureus ATCC# 6538, Pseudomonas aeruginosa ATCC 15442, Salmonella enterica ATCC 10708, Escherichia coli ATCC 11229 and Klebsiella pneumoniae ATCC 4352.

FUNGICIDAL ACTIVITY - When diluted at the rate of 1/2 ounces per gallon (1 part product to 255 parts water, or 4 ml product per 1000 ml of water), this product is also fungicidal against the pathogenic fungi, Candida albicans and Trichophyton interdigitale (causative agent of Athlete's Foot Fungus) when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, exercise facilities or other clean, hard, non-porous, surfaces commonly contacted by bare feet. Follow the Disinfection directions.

*VIRUCIDAL ACTIVITY – This product, when used on environmental, inanimate, hard, nonporous surfaces at 1/2 ounces per gallon (1 part product to 255 parts water, or 4 ml product per 1000 ml of water), exhibits effective virucidal activity against Avian Influenza A (H3N2) Reassortan virus ATCC VR-2072, Infectious Laryngotracheitis virus (strain LZT-IVAX), Newcastle disease virus ATCC VR-108, Pseudorabies virus ATCC VR-135, Porcine Respiratory & Reproductive Syndrome (PRRS) virus, Transmissible Gastroenteritis virus (TGE), Porcine Epidemic Diarrhea Virus (PEDV), and Human Immunodeficiency Virus Type 1 (HIV-1). Follow the Disinfection directions.

TUBERCULOCIDAL ACTIVITY – When diluted at the rate of 2 ounces per gallon (1 part product to 63 parts water, or 16 ml product per 1000 ml of water), this product exhibits disinfectant efficacy against Mycobacterium tuberculosis (Mycobacterium bovis ATCC 35743) at 20 degrees Centigrade (20°C) when the treated surface is allowed to remain wet for **10 minutes**.

KILLS HIV-1, HBV AND HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings (Hospitals, Nursing Homes) 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), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV). SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS. PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks, and eye coverings. CLEANING **PROCEDURES:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of (this product or product name). **CONTACT TIME:** Allow surface to remain wet for 10 minutes. **DISPOSAL OF INFECTIOUS MATERIALS:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

To clean and disinfect barber/beauty salon instruments and tools: Clean and disinfect hard, non-porous articles such articles as combs, brushes, razors and scissors. Wipe articles clean and soak for 10 minutes in the end-use solution.

Disinfection of Hard Non-Porous Surfaces in Whirlpool Foot Spas, Air-Jet Basins, "Pipe-less" Foot Spas, and other Circulating Spas: After using the whirlpool unit or foot spa, drain and preclean the interior surfaces to remove heavy soil, making sure to clean under rim and in crevices. Remove screen and all debris trapped behind the screen. Preclean and rinse screen and inlet. Prepare the disinfecting solution by refilling the unit with fresh water to just cover the intake valve and adding ½ oz of product per each gallon of water in the unit. Turn jets on for the 10 minutes contact time. Drain and rinse all surfaces with fresh water.

Disinfection of Tanning Beds: Preclean and rinse to remove heavy soil from surface. Apply the end-use solution with a cloth, sponge, or mechanical spray device, making sure all surfaces are wetted thoroughly. Treated surfaces must remain wet for 10 minutes. Rinse with fresh water.

Directions For Use In Poultry Houses for disinfection of hard non-porous surfaces:

- 1. Remove all poultry and feeds from premises, vehicles, enclosures, trucks, coops, and crates.
- 2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- **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 hard non-porous surfaces with the end-use solution for a period of 10 minutes. Use a mechanical spray device or apply layer of foam with foaming apparatus.

6. Ventilate buildings, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried.

7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers, and

mangers with the end-use solution. Rinse with potable water before reuse.

Directions For Use In Ratite Ranches, Aviaries, Swine Producing Facilities, Equine Facilities, Veal Barns, And Calving Operations for disinfection of hard non-porous surfaces.

1. Do not use in milking stalls, milking parlors, or milk houses.

2. Remove all animals, poultry and feed from premises, vehicles, trucks, coops, crates and enclosures.

- **3.** Remove all trucks, coops, crates, water troughs and feed racks.
- 4. Remove all gross soil, litter, manure and droppings from animals and poultry from floors, walls

and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals and poultry.

- 5. Empty all troughs, racks, and other feeding and watering appliances.
- 6. Thoroughly clean all surfaces with soap or detergent and rinse with water.

7. Saturate all hard non-porous surfaces with the end-use solution for a period of 10 minutes. Use a mechanical spray device or apply layer of foam with foaming apparatus.

8. Immerse handling and restraining equipment, forks, shovels, scrapers used for removing litter and manure, in the end-use solution. Allow to remain in contact for 10 minutes.

9. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.

10. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers, and mangers with the end-use solution. Rinse with potable water before reuse.

HATCHERIES: Use to treat hatchers, setters, trays, racks, carts, sexing tables, delivery trucks and other hard nonporous surfaces. Apply the end-use solution through automatic washing systems, immersion tanks, foaming apparatus, low pressure sprayers, and wet misting systems. Leave treated surfaces wet for 10 minutes or more. Allow to air dry.

Directions For Use In Bird Cages:

REMOVE BIRDS AND FOOD/WATER BOWLS FROM CAGE. To clean, disinfect and deodorize bird cages and cage floors, remove gross filth and bird droppings with a preliminary cleaning step prior to application of this product. To mix solution of this product using calibrated dropper, mix 2 ml of this product to 16oz. of water in any clean spray bottle. For larger solutions, mix 15

ml of this product per gallon of water. Spray or wipe making sure all surfaces are wetted thoroughly. Allow surface to remain wet for 10 minutes. Air dry. Return birds to cage.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. *Commercial Use:*

PESTICIDE STORAGE: Store only in original container away from heat or open flame. Keep container closed when not in use. Storage must be secured sufficiently to make product inaccessible to children or persons unfamiliar with its proper use. **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 - [For containers greater than 5 gallon]: 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. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available, or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities by burning. If burned, stay out of smoke.

[For containers equal to or less than 5 gallons]: 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 1/4 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 reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities by burning. If burned, stay out of smoke.

ENVIRONMENTAL HAZARDS

[For containers 5 gallons or greater]: This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, ponds, streams, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.