

11725-7

9/29/2003

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 29, 2003

Ms. Wendy A. McCombie, Lewis & Harrison Consultants for
Bio-Tek Industries, Inc.
c/o 122 C Street NW, Suite 740
Washington, DC 20001

Subject: ***Tek-Trol Disinfectant Cleaner Concentrate***
EPA Registration No. 11725-7
Application Dated June 30, 2003

Dear Ms. McCombie:

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

Proposed Amendment


- Update First Aid Statement per PR Notice 2001-1
- Revised BCP RED (dated 11/27/01)

General Comment

A stamped copy of the accepted labeling is enclosed.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422, or Lisa McKelvin at (703) 308-7496.

Sincerely,


Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

Enclosure

ACCEPTED
with COMMENTS
in EPA Letter dated
SEP 29 2003

No. 11725-7

TEK-TROL

DISINFECTANT • CLEANER • CONCENTRATE
STAPHYLOCIDAL • PSEUDOMONACIDAL • SALMONELLACIDAL
ASPERGILLOCIDAL • TUBERCULOCIDAL • VIRUCIDAL
FUNGICIDAL • PARVOCIDAL • MILDEWCIDAL • DEODORANT

ACTIVE INGREDIENTS:	
para-tertiary-Amylphenol	4.00%
ortho-Benzyl-para-chlorophenol	10.00%
ortho-Phenyphenol	12.00%
INERT INGREDIENTS:	74.00%
TOTAL:	100.0%

EPA REG. NO. 11725-7

EPA EST. NO. 11725-GA-1

**KEEP OUT OF REACH OF CHILDREN
DANGER**

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER. CORROSIVE. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Handlers must wear:

- Coveralls or long-sleeved shirt and long pants
- Socks and chemical-resistant shoes
- Goggles or face shield
- Chemical-resistant gloves

In addition, for applicators and other persons who may be exposed to the enclosed area has been treated with this product, wear protective clothing and equipment, including a full-face respirator, required in the precautionary statement section of this labeling for applicators and other handlers.

Follow general instructions on the label for use. Do not use in confined spaces. Do not use on electrical equipment.

RECOMMENDATIONS	
Users should:	
• Wash hands thoroughly after use.	
• Remove clothing immediately if contaminated.	
• Wash contaminated clothing before reuse.	
• Wash outside of shoes before reuse.	

FIRST AID	
IF IN EYES:	Flush eyes with water for at least 15 minutes. Get medical attention.
IF SWALLOWED:	Do not induce vomiting. Get medical attention.
IF ON SKIN OR ON CLOTHING:	Remove contaminated clothing. Wash skin with soap and water.
IF INHALED:	Move to fresh air. Get medical attention.
Have the product container or label with you when you call a doctor or go for treatment.	
NOTE TO PHYSICIAN:	Probable bacterial origin of the infection. Do not use antibiotic therapy.

PHYSICAL AND CHEMICAL HAZARDS

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

CONDUCTIVE

TEK-TROL has been tested by Hood Patterson-Dewar, Electrical Testing Engineers, for its effect on conductive flooring. The method used conforms to the specifications known as NFPA Standard No. 56A, published by the National Fire Protection Association, Second Edition, 1987. TEK-TROL meets the requirement of NFPA Standard No. 56A.

ENVIRONMENTAL HAZARDS

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.]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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. Thoroughly ventilate entire closed area after fogging applications. Do not enter, allow other persons to enter, house livestock, or use equipment in the treated area until ventilation is complete and any liquid has been absorbed, set, or dried. For entry into fogged areas before ventilation is complete and the fog has completely dissipated, all persons must wear the personal protective equipment, including a full-face respirator, required in the precautionary statement section of this labeling for applicators and other handlers.

General Information: TEK-TROL is a synthetic detergent with broad spectrum kill of gram positive and gram negative microorganisms, provides effective cleaning and disinfecting in one operation, non-flammable and non-volatile in use dilutions, excellent solubility, dilutes in hot, cold, soft or hard water of up to 1000 ppm water hardness.

The TEK-TROL high foaming detergent system 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 1/2 oz. per gallon of water (1:256) to provide prolonged contact time.

TEK-TROL, at 1/2 oz. per gallon of water (1:256) provides residual control of odor causing bacteria in the presence of moisture.

TEK-TROL 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 treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), polystyrene, vinyl, fiberglass, viton, ethylene propylene, nitrile, acrylic, and polyurethane.

TEK-TROL at 1/2 oz. per gallon of water (1:256) 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, rattle, 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 buses, 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. TEK-TROL can also be used as a wall and floor cleaner in poultry and meat processing plants, meat packing plants, frozen food and canning operations.

TEK-TROL is recommended for use in fogging (wet misting) operations as an adjunct sanitizer of room surfaces either preceding or following regular cleaning and disinfecting procedures. Use at a dilution of 1/2 oz. per gallon (1:256). Check with a Bio-Tek representative to determine effective fogging schedule for particular use sites. Leave the room when fogging. In well ventilated areas, such as hatcheries, only 10 to 15 minutes is necessary before reentering. If used in a poorly ventilated area, allow at least 2 hours, or air thoroughly, before reentry. Before fogging in food processing areas, all food and food packaging items must be removed or carefully protected. To thoroughly clean and disinfect room surfaces, before or after fogging, scrub with TEK-TROL at 1/2 oz. per gallon (1:256). Disinfected food contact surfaces must be rinsed with potable water prior to reuse.

Toxicity tests required by the U.S. Environmental Protection Agency for TEK-TROL DISINFECTANT-CLEANER have been done in conformity with the EPA Good Laboratory Practice Regulations.

Proven effective as a disinfectant by the following tests: A.O.A.C. (use dilution test method) in conformance with the 14th Edition 1984. All dilutions at 1:256. The following organisms tested at 1000 ppm water hardness (as calcium carbonate) and 10% horse serum (as organic soil):

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| <ul style="list-style-type: none"> Alicigenes faecalis, Strain# 638 Alicigenes faecalis, Georgia Strain Aspergillus fumigatus, ATCC# 6285 Beta streptococcus, ATCC#19615 Bordetella bronchiseptica, ATCC# 10580 Candida albicans, ATCC# 18804, A.O.A.C. Fungicidal Test Enterobacter aerogenes, ATCC# 13048 Enterococci Group D Species Vancomycin-Resistant Enterococcus faecalis (VRE), ATCC #51299 Escherichia coli, ATCC# 11229 Haemophilus parasuis, ATCC# 19417 Klebsiella pneumoniae, ATCC# 4352 Microsporium canis, ATCC# 42872, A.O.A.C. Fungicidal Test Microsporium gypseum, ATCC# 52027, A.O.A.C. Fungicidal Test Mycobacterium bovis (BCG), A.O.A.C. Tuberculocidal Test Mycoplasma synoviae Mycoplasma gallisepticum Mycoplasma hyopneumoniae, ATCC# 25934 Pasteurella anatispifer Pasteurella multocida, ATCC# 6529(fowl cholera) Proteus vulgaris, ATCC# 13315 Pseudomonas aeruginosa, ATCC# 15442 | <ul style="list-style-type: none"> Rhodococcus equi, ATCC#6939 Salmonella arizonae PD 36 Salmonella arizonae #7.1, 7.8 Salmonella choleraesuis, ATCC# 10708 Salmonella choleraesuis, Kunzendorf Strain Salmonella enteritidis, ATCC# 13076 Salmonella gallinarum, ATCC# 9184 Salmonella pullorum, ATCC# 19945 Salmonella schottmuelleri, ATCC# 8749 Salmonella typhimurium, ATCC# 13311 Shigella sonnei ATCC# 25931 Methicillin-Resistant Staphylococcus aureus (MRSA), ATCC # 33591 Staphylococcus aureus, ATCC# 6538 Staphylococcus epidermidis Staphylococcus hyicus Streptococcus equi, ATCC#39506 Streptococcus pyogenes, ATCC# 9342 Streptococcus pyogenes, ATCC#19615 Streptococcus suis, Type II Taylorella equigenitalis (C.E.M.), Kentucky Strain 3056 Trichophyton equinarum, ATCC# 64916 A.O.A.C. Fungicidal Test Trichophyton mentagrophytes, ATCC# 9533 A.O.A.C. Fungicidal Test |
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*The following Viruses tested in accordance with U.S. Environmental Protection Agency Pesticide Assessment Guidelines on hard, nonporous inanimate environmental surfaces. Tested at 1000 ppm water hardness (as calcium carbonate) and 10% serum (as organic soil):

Avian adenovirus
Avian infectious bronchitis virus
Avian influenza virus
Avian Laryngotracheitis
Avian reovirus
Avian rotavirus ATCC# VR-1
Canine adenovirus ATCC# VR-800
Canine coronavirus ATCC# VR-809
Canine parvovirus, Strain CPV MLV (Cornell)
Duck enteritis virus (D.V.E.)
Equine arteritis, ATCC#VR-796 (Equine viral arteritis)
Equine herpes virus, ATCC#VR-700 (Equine rhinopneumonitis)
Equine Rotavirus

Feline calicivirus, ATCC# VR-782
Feline rhinotracheitis ATCC# VR-636
Herpes Simplex Type 1
HIV-1 (AIDS virus)
Influenza A-2/Hong Kong virus, ATCC# VR-574
Mouse hepatitis virus, Strain MHV-A59, ATCC # VR-764
Newcastle disease virus
Parainfluenza virus, Type I, Sendai Strain ATCC# VR-105
Porcine Reproduction and Respiratory Syndrome Virus, Strain ISU-P ATCC #VR-2402
Porcine rotavirus, ATCC#VR-893
Pseudorabies virus, Aujeszky Strain, ATCC# VR-135
Transmissible gastroenteritis virus, Purdue Strains, ATCC# VR-763

Hard Surface Mildewcidal Test Method: CSMA method 23 at 1000 ppm water hardness (as calcium carbonate) and 10% horse serum (as organic soil):

Aspergillus niger ATCC# 6275 (black mold) Penicillium variable NRRL# 3765 (Green mold)

General Use Directions:

1. To clean, disinfect and deodorize walls, floors, tables, drinking fountains, sinks, refrigerators, stoves, restroom fixtures and garbage cans. Remove gross filth and heavy soil with a preliminary cleaning step prior to application of TEK-TROL. Apply solution of 1/2 oz. of TEK-TROL per gallon of water (1:256) 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 such articles as food and water bowls, non-porous bird toys, non-porous perches, combs, brushes, razors, scissors, 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 in a solution containing 1/2 oz. TEK-TROL per gallon of water (1:256). Rinse food and water bowls prior to reuse.
 3. To disinfect fabrics such as sheets, linens, aprons and uniforms: First rinse to remove gross filth or heavy soil, then soak for 10 minutes in a solution containing 1/2 oz. of TEK-TROL per gallon of water (1:256).
 4. To clean gross filth or heavy soil on environmental surfaces prior to disinfection, use 1/2 oz. of TEK-TROL per gallon of water (1:256).
 5. Dilution ratios: use 1/4 oz. (15cc) of TEK-TROL per gallon of water (1:256) [use 1/16 oz (2cc) of TEK TROL per 16 oz. of water (1:256); 1/8 oz (4cc) TEK TROL per 32 oz. of water (1:256); 3/16 oz. (6cc) of TEK-TROL per 48 oz of water (1:256)].
- BIO-TEK INDUSTRIES, INC., recommends the use of the BIO-TEK proportioner to provide the automatic method to obtain the 1/2 oz. per gallon solution (1:256).

Hospital Use Directions:

1. To clean, disinfect, and deodorize walls and other hard non-porous environmental surfaces, use 1/2 oz. of TEK-TROL per gallon of water (1:256). Apply with cloth, sponge, mop, mechanical spray device or foaming apparatus, making sure all surfaces are wetted thoroughly. Allow surface to remain wet for 10 minutes. For heavily soiled areas a preliminary cleaning is required, remove gross soil and proceed per above.
2. After treatment, rinse surfaces with potable water.
3. TEK-TROL is an effective tuberculocide against Mycobacterium bovis in 10 minutes at 20° C when used on hard non-porous inanimate environmental surfaces. Follow above directions, including removal of gross filth or heavy soil prior to application of TEK-TROL.
4. KILLS 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 I (HIV-1) (associated with AIDS).

Special Instructions For Cleaning And Decontamination Against Hiv Of Surfaces/ Objects Soiled With Blood/Body Fluids:

- PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use protective equipment such as disposable rubber gloves, gowns, masks or eye coverings.
- CLEANING PROCEDURE: Blood or body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.
- CONTACT TIME: To kill HIV-1 (AIDS virus) a contact time of 10 minutes at room temperature must be allowed.
- DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

Hatching Egg Sanitizer: TEK-TROL is recommended for use as a Hatching Egg Sanitizer, with best results being achieved in water temperatures ranging from 78°F to 110°F. The recommended dilution is 1/2 oz. per gallon of water (1:256), and may be applied through automatic washing systems, immersion tanks, foaming apparatus, low pressure sprayers, and fogging (wet misting) systems.

Directions For Use In Farm Premises:

1. Do not use in milking stalls, milking parlors, or milk houses.
2. Remove all animals and feed from premises, vehicles, and enclosures.
3. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
4. Empty all troughs, racks, and other feeding and watering appliances.

5. Thoroughly clean all surfaces with soap or detergent and rinse with water.
6. Saturate all surfaces with a solution of 1/2 oz. of TEK-TROL per gallon of water (1:256) for a period of 10 minutes. Use high pressure sprayer or apply layer of foam with BIO-TEK foaming apparatus.
7. Immerse halters, ropes and other types of equipment used in handling and restraining animals, forks, shovels, scrapers used for removing litter and manure, in a solution of TEK-TROL at 1/2 oz. per gallon of water (1:256). Allow to remain in contact for 10 minutes.
8. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
9. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers, and mangers with a solution of TEK-TROL at 1/2 oz. per gallon of water (1:256). Rinse with potable water before reuse.

Directions For Use In Poultry Houses:

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 surfaces with a solution of 1/2 oz. of TEK-TROL per gallon of water (1:256) for a period of 10 minutes. Use high pressure sprayer or apply layer of foam with BIO-TEK 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 a solution of TEK-TROL at 1/2 oz. per gallon of water (1:256). Rinse with potable water before reuse.

Directions For Use In Ratite Ranches, Aviaries, Swine Producing Facilities, Equine Facilities Veal Barns, And Calving Operations:

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 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.
4. Empty all troughs, racks, and other feeding and watering appliances.
5. Thoroughly clean all surfaces with soap or detergent and rinse with water.
6. Saturate all surfaces with a solution of 1/2 oz. of TEK-TROL per gallon of water (1:256) for a period of 10 minutes. Use high pressure sprayer or apply layer of foam with BIO-TEK foaming apparatus.
7. Immerse halters, ropes and other types of equipment used in handling and restraining animals, forks, shovels, scrapers used for removing litter and manure, in a solution of TEK-TROL at 1/2 oz. per gallon of water (1:256). Allow to remain in contact for 10 minutes.
8. Ventilate buildings, cars, boats, and other closed spaces. Do not house livestock or employ equipment until treatment has been absorbed, set, or dried.
9. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers, and mangers with a solution of TEK-TROL at 1/2 oz. per gallon of water (1:256). Rinse with potable water before reuse.

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 TEK-TROL. To mix solution of TEK-TROL using calibrated dropper, mix 2 cc of TEK-TROL to 16 oz. of water in the TEK-TROL spray bottle or any other clean spray bottle. For larger solutions, mix 1/4 oz. (15 cc) per gallon of water (1:256). 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.
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 Disposal: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Do not reuse empty container.

ACCEPTED
with COMMENTS
EPA Letter Dated:
Net Contents

Manufactured by: BIO-TEK INDUSTRIES, Inc.
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Atlanta, GA 30318
Telephone 404-799-2050
FAX: 404-799-2058 www.bio-tekusa.com

SEP 29 2003

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 11725-7

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