

09 FEB 1993

Octavia A. Hollaway
Bio-Tek Industries, Inc.
1380 West Marietta Street NW
P.O. Box 93746
Atlanta, GA 30318

Subject: Tek-Trol Disinfectant Cleaner Concentrate
EPA Registration No. 11725-7
Your Amendment Dated December 16, 1992

Dear Ms. Hollaway:

This is in response to your amended labeling -- changes in the Directions for Use in response to the California Department of Food and Agriculture.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comment below. A stamped copy is enclosed for your records.

Submit five copies of the finished labeling before you release the product for shipment bearing the amended labeling.

If you have any questions about this letter, you may call Wallace Powell at (703) 305-6938.

Sincerely,



Ruth G. Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (H-7504C)

Enclosure

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							



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with COMMENTS
in EPA Letter Dated:

PM 32

11725-7

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

11725-7

LEFT PANEL

TEK-TROL DISINFECTANT-CLEANER CONCENTRATE

DESCRIPTION

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 non-porous surfaces such as treated wood, polyethylene, 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 ideally suited for disinfecting and cleaning in all areas of Hospitals, Medical Research Centers, Health Care Facilities, Schools, Animal Care Facilities and Research Centers, Laboratories, Veterinary Facilities, Zoos, Kennels, and Swine Operations. In Food Processing Plants as a floor and wall cleaner - in poultry processing, meat packing plants, frozen food and canning operations, in poultry and turkey barns, Breeder and Laying Operations. Poultry House Grow-out Operations, Hatcheries - 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 including stables, stalls, breeding and foaling areas and transport vehicles.

TEK-TROL is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. Use 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. Treated food contact surfaces must be thoroughly scrubbed with **TEK-TROL** at 1/2 oz. per gallon (1:256) and rinsed with potable water prior to reuse.

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Toxicity tests required by the U. S. Environmental Protection Agency for TEK-TROL DISINFECTANT-CLEANER have been done, in conformity with the EPA and 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):

- | | |
|--|--------------------------------------|
| Staphylococcus aureus ATCC #6538 | Salmonella enteritidis ATCC #13076 |
| Streptococcus pyogenes ATCC #9342 | Aspergillus fumigatus ATCC #6285 |
| Shigella sonnei ATCC #25931 | Salmonella choleraesuis ATCC #10708 |
| Klebsiella pneumoniae ATCC #4352 | Salmonella schottmuelleri ATCC #8749 |
| Enterobacter aerogenes ATCC #13048 | Salmonella pullorum ATCC #19945 |
| Proteus vulgaris ATCC #13315 | Salmonella gallinarum ATCC #9184 |
| Pseudomonas aeruginosa ATCC #15442 | Salmonella typhimurium #13311 |
| Mycobacterium bovis (BCG) | Salmonella arizonae #7:1, 7, 8 |
| A.O.A.C. Tuberculocidal Test | Salmonella arizonae PD 36 |
| Trichophyton mentagrophytes ATCC #9533 | Escherichia coli ATCC #11229 |
| A.O.A.C. Fungicidal Test | Alcaligenes faecalis Strain #838 |
| Pasteurella multocida ATCC #6529 | Alcaligenes faecalis Georgia Strain |
| (fowl cholera) | Staphylococcus epidermis |
| Pasteurella anatipestifer | Enterococci Group D Species |
| Beta streptococcus, ATCC #19615 | Mycoplasma gallisepticum |
| Mycoplasma synoviae | Staphylococcus hyicus |
| Rhodococcus equi, ATCC #6939 | Streptococcus equi, ATCC #39506 |
| Salmonella choleraesuis | Streptococcus suis, Type II |
| Kunzendorf Strain | Streptococcus pyogenes, ATCC #19615 |
| Taylorella equigenitalis (C.E.M.) | |
| Kentucky Strain 3056 | |

+The following Viruses tested in accordance with U.S. Environmental Protection Agency Pesticide Assessment Guidelines on inanimate environmental surfaces. Tested at 1000 ppm water hardness as calcium carbonate and 10% serum (as organic soil):

- | | |
|---------------------------------------|---|
| --Herpes Simplex Type I | --Newcastle disease virus |
| --Avian infectious bronchitis virus | --Avian influenza virus |
| --Transmissible gastroenteritis virus | --Pseudorabies virus, Aujeszky Strain, |
| Purdue Strains, ATCC #VR-763 | ATCC #VR-135 |
| --Canine parvovirus, Strain CPV MLV | --Mouse hepatitis virus, Strain MHV-A59 |
| (Cornell) | ATCC #VR-764 |
| --Parainfluenza virus, Type I | --Avian adenovirus |
| Sendai Strain ATCC #VR-105 | --Equine herpes virus, ATCC #VR-700 |

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(2)

- Avian reovirus
- Porcine rotavirus, ATCC #VR-893
- Avian rotavirus, ATCC #VR-1
- Duck enteritis virus (D.V.E.)
- Avian Laryngotracheitis

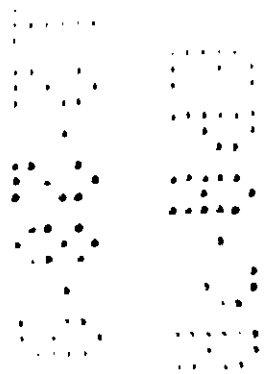
- (Equine rhinopneumonitis)
- Equine arteritis, ATCC #VR-796
(Equine viral arteritis)
- Influenza A-2/Hong Kong virus,
ATCC #VR-544
- HIV-1 (AIDS virus)

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)

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CENTER PANEL
TEK-TROL DISINFECTANT-CLEANER CONCENTRATE

TEK-TROL

DISINFECTANT - CLEANER CONCENTRATE

**FOR USE IN POULTRY, SWINE, EQUINE, VEAL, AVIAN, VETERINARY,
AND ANIMAL CARE FACILITIES**

STAPHYLOCIDAL PSEUDOMONACIDAL SALMONELLACIDAL
ASPERGILLOCIDAL TUBERCULOCIDAL VIRUCIDAL FUNGICIDAL
PARVOCIDAL MILDEWCIDAL DEODORANT

ACTIVE INGREDIENTS:

ortho-Phenylphenol	12.0%
ortho-Benzyl-para-chlorophenol	10.0%
para-tertiary-Amylphenol	4.0%

INERT INGREDIENTS:

74.0%

TOTAL 100.0%

EPA REG. NO. 11725-7

EPA EST. NO. 11725-GA-1

**PROVEN EFFECTIVE IN 10% BLOOD SERUM
AND 1000 PPM WATER HARDNESS**

KEEP OUT OF REACH OF CHILDREN

**DANGER
PRECAUTIONARY STATEMENTS:**

Hazard to Humans and Domestic Animals

**DANGER. Corrosive. Causes eye and skin damage. Do not get in eyes,
on skin, or on clothing. Wear goggles or face shield and rubber gloves
when handling. May be harmful or fatal if swallowed. Wash thoroughly
with soap and water after handling and before eating, drinking or using
tobacco. Remove contaminated clothing and wash before reuse.**

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Statement of Practical Treatment

If on Skin - Wash with plenty of soap and water. Get medical attention.

If in Eyes - Hold eyelids open and flush eyes with plenty of water. Get medical attention.

If Swallowed - Call a physician immediately. Drink large quantities of water. Never give anything by mouth to an unconscious person. Avoid Alcohol.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

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 56A.

Manufactured by:

LOGO

**BIO-TEK INDUSTRIES, INC.
1380 West Marietta Street, N.W.
Atlanta, GA 30318, USA
Telephone (404) 799-2050 Telex: 671-2844
FAX: (404) 799-2058**

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RIGHT PANEL

TEK-TROL DISINFECTANT-CLEANER CONCENTRATE

DIRECTIONS FOR USE

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

HOSPITAL USE DIRECTIONS:

1. To clean, disinfect, and deodorize walls and other non-porous 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. When completed rinse with clear water.
3. TEK-TROL is an effective tuberculocide against Mycobacterium bovis in 10 minutes at 20 C when used on hard, non-porous inanimate 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.

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- 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.

GENERAL USE DIRECTIONS:

1. To clean, disinfect and deodorize walls, floors, tables, drinking fountains, sinks, refrigerators, stoves, rest room 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, razor scissors, instruments and rubber goods: All instruments and devices 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 surfaces prior to disinfection, use 1/2 oz. of TEK-TROL per gallon of water (1:256).
5. Dilution ratios: use 1/2 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) of TEK-TROL per 32 oz. 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).

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DIRECTIONS FOR USE IN POULTRY HOUSES, FARM PREMISES, SWINE PRODUCING FACILITIES, EQUINE FACILITIES AND VEAL BARNs:

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

1. Remove all animals and feed from the premises.
2. Remove all trucks, coops, crates, water troughs and feed racks.
3. Remove all gross soil, litter, manure, 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. Thoroughly clean and saturate all surfaces with a solution of 1/2 oz. of TEK-TROL per gallon of water (1:256). Use high pressure sprayer or apply layer of foam with BIO-TEK foaming apparatus.
5. Allow to remain in contact for at least ten minutes.
6. 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.
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.
8. Ventilate buildings, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.

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 2cc of TEK-TROL to 16 oz. of water in the TEK-TROL spray bottle or any other clean spray bottle. For larger solutions, mix 1/2 oz. (15cc) 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.

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STORAGE AND DISPOSAL

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.

Do not contaminate water, food, or feed by storage or disposal.

Container Disposal - - Triple rinse (or equivalent). Then offer for recycling 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.

NET CONTENTS _____ U. S. GALLONS

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