

PM32 11725-7

10/11

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1 FEB 1994

Biotek Industries, Inc.  
1380 West Marietta Street, N.W.  
Atlanta, GA 30318

Attn: Joyce B. Pazianos,  
Authorized Agent for Biotek Industries, Inc.

Subject: Tektrol Disinfectant-Cleaner Concentrate  
EPA Reg. No. 11725-7  
Your Amendment of June 30, 1993

The efficacy data submitted in support of the proposed amendment to expand the subject product labeling by adding animal pathogen claims has completed review. The following comments are based on our review of the submitted data and revised labeling.

1. The submitted microbiological data supports the product effectiveness on hard non-porous surfaces, in accordance with label directions, against the following organisms: Bordetella bronchiseptica, Microsporum canis, Microsporum gypseum, Candida albicans, and Trichophyton equinarum.

2. The submitted virucidal data developed under the EPA Virucidal Test Method (DIS/TSS-7, Nov. 1981) are supportive of the subject product's effectiveness, in accordance with label directions, against the following viruses: Canine adenovirus, Equine rotavirus, Feline calcivirus, Feline rhinotracheitis, Canine coronavirus.

3. The revised product labeling, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records. Submit one copy the final printed labeling, which incorporates these comments, before releasing the product for shipment with the revised labeling.

a. On the center panel of the draft label, (page 4), the signal word, "DANGER" beneath the "Keep Out Of Reach of Children" warning, must be in type which is larger than the surrounding text.

CONCURRENCES

SYMBOL	705C						
SURNAME	Pazianos						
DATE	1 FEB 1994						

b. On the left hand panel (page 1), in the fourth paragraph, and in the right hand panel (page 6), second paragraph; revise the wording "other non-porous surfaces" to read: "other hard non-porous surfaces".

c. In the Use Directions of page 6 you must also indicate if and how the product must be removed after the 10 minute exposure time. Refer to item 6 of the enclosed DIS/TSS-15 bulletin.

d. On the left hand panel (page 1), delete the word "ideally" from the first sentence of the fifth paragraph. Superlatives relating to product effectiveness such as "ideal" and "superior" are considered misleading and are not acceptable.

e. In the sixth paragraph of the left hand panel, (page 1), revise the first sentence "Tektrol is recommended..." to read: "Tektrol is recommended for use in fogging (wet misting) operations of room surfaces as an adjunct sanitizer either preceding or following regular cleaning and disinfecting procedures.". Revise the first part of the last sentence of this paragraph to read: "Disinfected food contact surfaces must be ....". (Note that sanitization of food contact surfaces would not require a potable water rinse.)

e. On page 3 of the left hand panel of the label, revise the first sentence "The following Viruses ..." to read: "The following viruses tested in accordance with U.S. Environmental Protection Agency Pesticide Assessment Guidelines on hard non-porous inanimate environmental surfaces.".

A copy of the efficacy evaluation review performed on this amendment request is enclosed.

If you should have any questions concerning this letter, you may call Robert Travaglini on (703) 305-6909.

Sincerely,



Ruth G. Douglas  
Product Manager (32)  
Antimicrobial Program Branch  
Registration Division (7505C)

ACCEPTED  
W/CC/STARS  
in EPA Label Database

31 FEB 1994

Under  
Permit  
No. 1125-7  
EPA Reg. No.

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: 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 and breeder barns, laying operations, and hatcheries, including hatcher 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, healthcare 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 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

(1)

BEST AVAILABLE COPY

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.

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 A.O.A.C. use dilution test method. All dilutions at (1:256). The following organisms tested at 1000 ppm water hardness (as calcium carbonate) and 10% horse serum (as organic soil):

- |  |  |
|--|--|
| Alcaligenes faecalis Strain #838       | Salmonella choleraesuis ATCC #10708    |
| Alcaligenes faecalis Georgia Strain    | Salmonella choleraesuis                |
| Aspergillus fumigatus ATCC #6285       | Kunzendorf Strain                      |
| Beta streptococcus, ATCC #19615        | Salmonella enteritidis ATCC #13076     |
| Bordetella bronchiseptica, ATCC #10580 | Salmonella gallinarum ATCC #9184       |
| Candida albicans, ATCC #18804          | Salmonella pullorum ATCC #19945        |
| A.O.A.C. Fungicidal Test               |  |
| Enterobacter aerogenes ATCC #13048     | Salmonella schottmuelleri ATCC #8749   |
| Enterococci Group D Species            | Salmonella typhimurium #13311          |
| Escherichia coli ATCC #11229           | Shigella sonnei ATCC #25931            |
| Klebsiella pneumoniae ATCC #4352       | Staphylococcus aureus ATCC #6538       |
| Microsporium canis, ATCC #42872        | Staphylococcus epidermis               |
| A.O.A.C. Fungicidal Test               |  |
| Microsporium gypseum, ATCC #52027      | Staphylococcus hyicus                  |
| A.O.A.C. Fungicidal Test               |  |
| Mycobacterium bovis (BCG)              | Streptococcus equi, ATCC #39506        |
| A.O.A.C. Tuberculocidal Test           |  |
| Mycoplasma synoviae                    | Streptococcus pyogenes ATCC #9342      |
| Mycoplasma gallisepticum               | Streptococcus pyogenes, ATCC #19615    |
| Pasteurella anatipestifer              | Streptococcus suis, Type II            |
| Pasteurella multocida ATCC #6529       | Taylorella equigenitalis (C.E.M.)      |
| (fowl cholera)                         | Kentucky Strain 3056                   |
|  | Trichophyton equinarum, ATCC #64916    |
|  | A.O.A.C. Fungicidal Test               |
| Proteus vulgaris ATCC #13315           | Trichophyton mentagrophytes ATCC #9533 |
| Pseudomonas aeruginosa ATCC #15442     | A.O.A.C. Fungicidal Test               |
| Rhodococcus equi, ATCC #6939           |  |
| Salmonella arizonae PD 36              |  |
| Salmonella arizonae #7:1, 7, 8         |  |



+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):

- 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 I
- HIV-1 (AIDS virus)
- Influenza A-2/ Hong Kong virus, ATCC #VR-544
- Mouse hepatitis virus, Strain MHV-A59 ATCC #VR-764
- Newcastle disease virus
- Parainfluenza virus, Type I, Sendai Strain ATCC #VR-105
- 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)

ACCEPTED  
with COMMENTS  
by EPA Lab Director  
FEB 1984

U.S. Environmental Protection Agency  
Federal Insecticide, Fungicide, and Rodenticide Act  
Registered under FIFRA Reg. No.  
11735-7

60711

**CENTER PANEL  
TEK-TROL DISINFECTANT-CLEANER CONCENTRATE**

**TEK-TROL**

**DISINFECTANT - CLEANER CONCENTRATE**

**FOR USE IN POULTRY, SWINE, EQUINE, VEAL, AVIAN, VETERINARY,  
RATITE, CALVING, 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%

**APPROVED  
with CONCISE  
in EPA Letter Dated:**

**L 1 FEB 1994**

**INERT INGREDIENTS:**

74.0%

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

**TOTAL 100.0%**

**11725-7**

**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.**

(4)

**BEST AVAILABLE COPY**

### 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

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

FEB 1994

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

11725-7

**BEST AVAILABLE COPY**

**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.

**BEST AVAILABLE COPY**



- 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, razors, 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).

**BEST AVAILABLE COPY**

**DIRECTIONS FOR USE IN POULTRY HOUSES, RATITE RANCHES, AVIARIES,  
FARM PREMISES, SWINE PRODUCING FACILITIES, EQUINE FACILITIES,  
VEAL BARN, AND CALVING OPERATIONS.**

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, and animal/poultry droppings from floors, walls floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals/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.



110/11

### 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

ACCEPTED  
FOR CONFINEMENT  
IN EPA LEACH DRAIN

FEB 1977

State of ...  
registered and ...  
approved for the ...  
registered under EPA Reg. ...

11735-7

**BEST AVAILABLE COPY**