

PMA 32 -25.7 1/10

APR - 7 1989

Pazianos Associates
1338 G Street SE.
Washington, DC 20003

Attention: Joyce B. Pazianos

Gentlemen:

Subject: Tek-Trol Disinfectant-Cleaner Concentrate
EPA Registration No. 31725-7
Your Amendment³ Dated ~~November 4~~ ^{December 28}, 1988 and September 16, 1988
EPA Received Date ~~November 4~~ ^{December 28}, 1988 and September 16, 1988

This is in response to the above-mentioned amendment. The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable subject to the comments listed below. Five (5) copies of the finished labeling must be submitted.

1. The submitted data developed by the Modified A.O.A.C. Use-Dilution Test appear adequate to support the effectiveness of the product as a disinfectant against Pasteurella multocida, Enterococci Group D, Staphylococcus epidermis, and Salmonella enteriditis at a 1:256 dilution in the presence of 1000 parts per million (ppm) hard water (as CaCO₃) and 10% blood serum on moderately soiled, hard, nonporous surfaces for a contact time of 10 minutes.

However, the submitted data for Salmonella enteriditis are insufficient because data were derived on only one of the two samples required. See 2 below.

The submitted data developed by the EPA Guidelines appear adequate to support the effectiveness of the product as a disinfectant against the virucide Parainfluenza 1, Strain Sendai at a 1:256 dilution in the presence of 1000 ppm hard water (as CaCO₃) and undiluted allantoic fluid equivalent to 10% blood serum on moderately soiled, hard, nonporous surfaces for a contact time of 10 minutes.

57061:I:Dutch:LK-17:KENCO:04/05/89:04/14/89:aw:VO:JH:AS

CONCURRENCES

SYMBOL	13-7504-C						
SURNAME	V. Dutch						
DATE	4-7-89						

2. In order to fulfill the efficacy data requirements for the bactericidal tests, one additional sample must be tested against Salmonella enteriditis in the presence of 1000 ppm hard water (as CaCO_3) and 10% blood serum. Provide the survival of control carriers after drying.
3. Label efficacy claims against microorganisms of aesthetic significance (such as odor-causing bacteria and mold/mildew) or against animal pathogens are not health-related uses and submission of supporting efficacy data are not required as explained in the DIS/TSS-16 enclosure.

Labeling

In lieu of data, delete Salmonella enteriditis.

Should you have any further questions, please contact Veronica Dutch at (703) 557-6738.

Sincerely yours,



Jeff Kempter
Product Manager (32)
Antimicrobial Program Branch
Registration Division (H7504C)

Enclosure

TEK-TROL

DISINFECTANT - CLEANER CONCENTRATE

• STAPHYLOCIDAL • PSEUDOMONACIDAL • ~~SALMONELLACIDAL~~ *OK*

ASPERGILLOCIDAL • TUBERCULOCIDAL • VIRUCIDAL +

FUNGICIDAL • MILDENCIDAL • DEODORANT • BIODEGRADABLE*

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

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

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS:

Hazard to Humans and Domestic Animals

Danger. Corrosive. Causes eye and skin damage or
skin irritation.

Do not get in eyes, on skin, or on clothing. Wear
goggles or face shield and rubber gloves when
handling.

Harmful or fatal if swallowed.

Statement of Practical Treatment

FIRST AID: In case of contact immediately flush eyes or skin with
plenty of water for at least 15 minutes. For eyes,
call physician. Remove and wash contaminated clothing
before reuse. If swallowed, drink promptly
large quantities of water. Avoid alcohol and call
a physician.

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

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• CONDUCTIVE •

Classified by Underwriters Laboratories, Inc. as approved for use as to electrical conductivity when used on conductive floors and spontaneous heating 321L. For use with electrically conductive flooring of the vinyl type.

Manufactured by:

LOGO

BIO-TEK INDUSTRIES, Inc.
1275 Ellsworth Industrial Dr., N.W.; Atlanta, GA 30318, USA
Telephone (404) 351-7048 Telex: 671-2844
FAX: 4043529091

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DESCRIPTION

TEK-TROL is a synthetic detergent with broad spectrum kill of gram positive and gram negative microorganisms, provides outstanding 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. After this products use as a disinfectant, it will biodegrade in sewage systems and/or the environment.*

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 as treated wood, vinyl and most plastics.

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 burns, Breeder and Laying Operations, Poultry House Grow-out Operations, Hatcheries-in hatchers and setters, evaporative coolers, humidifying systems, ceiling fans, live haul equipment, chick busses, transfer trucks, trays, coop washing, plastic chick boxes, foot pans and feed bins.

TEK-TROL is recommended for use in fogging (wet misting) operations as an adjunct either preceding or following regular cleaning and disinfecting procedures. The recommended dilution is 1/2 oz. per gallon of water (1:256). Set the automatic timer on the BIO-TEK Fogger, fog for 8 minutes for 1000 cu. ft.-leave the room. Allow at least 2 hours before entering area that has been fogged. Before fogging in food processing area, 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 FDA 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	Mycoplasma gallisepticum
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 ATCC# 13311
Mycobacterium bovis (BCG)	Salmonella arizonae #7:1, 7, 8
A.O.A.C. Tuberculocidal Test	Salmonella arizonae PD 36
Chytridiomycota/Chytridiomycetes ATCC# 9533	Salmonella enteritidis ATCC# 13076
A.O.A.C. Fungicidal Test	Escherichia coli ATCC# 11229
	Alcaligenes faecalis Strain# 838
	Alcaligenes faecalis Georgia Strain
	Staphylococcus epidermis
	Enterococci Group D Species
	Pasteurella multocida ATCC# 6529
	(fowl cholera)
	Pasteurella anatipestifer

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Under the Federal Insecticide,
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registered under EPA Reg. No.

+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 1	- Avian Laryngotracheitis
- Avian Infectious bronchitis virus	- Newcastle disease virus
- Transmissible gastroenteritis virus	- Avian Influenza virus
- Purdue Strains, ATCC# VR-763	- Pseudorabies virus, Aujeszky Strain
- Canine parvovirus, Strain CPV MLV (Cornell)	ATCC# VR-135
- Parainfluenza virus, Type 1,	- Mouse hepatitis virus, Strain MHV-A59
- Sendai Strain ATCC# VR 105	ATCC# VR-764
- Avian reovirus	- Avian adenovirus

Influenza A-2 Hong Kong virus tested at 500 ppm water hardness as calcium carbonate and 10% serum (as organic soil).

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Hard Surface Mildewicidal Test Method; CSMA method 28 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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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.

BIO-TEK INDUSTRIES, INC., recommends the use of the BIO-TEK portioner to provide the automatic method to obtain the 1/2 oz. per gallon solution (1:256).

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, 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.
2. To clean and disinfect such articles as combs, brushes, razors, scissors, instruments and other goods: Wipe articles clean and soak for 10 minutes in a solution containing 1/2 oz. TEK-TROL per gallon of water (1:256).

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).

DIRECTIONS FOR USE IN POULTRY HOUSE AND FARM PREMISE:

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

1. Remove all poultry, 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.

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STORAGE AND DISPOSAL

Pesticide Disposal — Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinseate 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 disposal.

Container Disposal — Plastic: 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.

CONTENTS _____ U.S. GALLONS

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