

Bio-Labs, Inc.
P.O. Box 1489
Decatur, GA 30031

SEP 28 1988

Attention: James R. Brown
Regulatory Affairs Specialist

Gentlemen:

Subject: Response to Tuberculocidal Data Call-In Notice
Bio-Guard X-185
EPA Registration No. 5185-334
Your Submission Dated July 28, 1988

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you make the following labeling revision before you release the product for shipment bearing the amended labeling.

- We recommend that you revise the ingestion statement by deleting "of milk."

Submit the final printed labeling for inclusion in the product file.

A stamped copy of the label is enclosed for your records.

If you have any questions in this regard, please contact Ms. Ruth Douglas at (703) 557-3842.

Sincerely yours,



Jeff Kempter
Product Manager (32)
Antimicrobial Program Branch
Registration Division (TS-767C)

Enclosure

57104:I:Douglas:LK-10;KENCO:9/27/88:10/7/88:AS:VO:AS

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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5185-334

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BIOGUARD®
X-185®

FOR USE IN POULTRY, SWINE, VEAL, DAIRY, CATTLE, CANINE AND HORSE
OPERATIONS.
FUNGICIDE, TUBERCULOCIDE

ACTIVE INGREDIENTS

Cresylic acid	30.0%
o-phenylphenol	4.0%
o-benzyl-p-chlorophenol	3.0%
tributyltin neodecanoate	0.5%

INERT INGREDIENTS: 62.5%

TOTAL INGREDIENTS 100.0%

*Includes water, soap, isopropanol, and synthetic detergents for hard water effectiveness.

DANGER
KEEP OUT OF REACH OF CHILDREN
(See practical treatment and precautions on back panel).

MANUFACTURED BY
BIO-LAB, INC. Decatur, Georgia 30031 USA

NET CONTENTS: 5 U.S. Gals. (18.95 l.)

ACCEPTED
with COMMENTS
In EPA Letter Dated:

SEP 28 1988

United States Environmental Protection Agency
Registration Division
Washington, D.C. 20460
5185-334

BioGuard® X-185™ is an effective farm disinfectant and a powerful detergent. It effectively cleans and disinfects in water up to 1,000 ppm hardness and a 5% organic soil load.

The germicidal ingredients include the saponified cresylics, substituted phenolics and tributyltin neodecanoate, providing broad spectrum killing action against most common poultry and livestock disease organisms.

BROAD-SPECTRUM BACTERIAL ACTION UNDER SOIL LOAD CONDITIONS.

At a 1 to 200 dilution in official A.O.A.C. Use Dilution Test, X-185 is effective in water up to 1,000 ppm hardness, as CaCO_3 and an organic soil load of 5% blood serum as a disinfecting agent against the following organisms:

Staphylococcus aureus	ATCC 6538
Salmonella choleraesuis	ATCC 10708
Pseudomonas aeruginosa	PRD 10
Salmonella typhosa	ATCC 6539
Escherichia coli	ATCC 11229

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TUBERCULOCIDAL. Using the A.O.A.C. Tuberculocidal Test Method, X-185 is an effective germicide at a dilution of 1:100 (2oz. to 1½ gals. of water) in 10 minutes at 20°C against *Mycobacterium Tuberculosis* var. *bovis* B.C.G. on precleaned surfaces.

PATHOGENIC FUNGICIDE. Using the A.O.A.C. Fungicidal Test Method, X-185 is an effective, pathogenic fungicide at a dilution 1:100 (2oz. to 1½ gals. of water) in the presence of 400 ppm hard water and light to moderate soil loads. On precleaned, hard non-porous, inanimate surfaces X-185 was found to be an effective pathogenic fungicide at a dilution of 1:200 (2 oz. to 3 gals. of water).

DIRECTIONS FOR USE

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

POULTRY, SWINE, VEAL, DAIRY, CATTLE, CANINE AND HORSE OPERATIONS:

Use X-185 for cleaning and disinfecting: broiler houses, brooders, layer houses, livestock barns, farrowing pens, foaling pens, stalls, calf hutches, pig parlors, kennels, poultry crates, animal transport vehicles and farm equipment.

X-185 is recommended for use on hard, non-porous inanimate surfaces such as finished concrete, finished wood, plastic, glazed tile, enameled, and metal surfaces of livestock handling equipment, housing and transportation equipment.

APPLICATION INFORMATION

Poultry and livestock must be removed from the premises during treatment. Do not rehouse poultry or livestock before treatment has dried. Feeders and waterers should be removed from houses during treatment. When it is not possible remove feeders and waterers, clean and rinse to remove all disinfectant residues before reuse. Avoid contact with feed or food contact surfaces. When appropriate, always remove gross soil by hosing with water, brushing, vacuuming, or sweeping before using X-185 for cleaning and disinfecting. Apply disinfecting solution with a brush, sponge, mop or by flushing with water under pressure. For hand use, wear rubber gloves. For disinfection, treated surfaces must remain moist for at least 10 minutes at 20°C. Spraying of the product is not recommended unless the operator is protected from breathing the spray mist.

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If tuberculocidal effectiveness is intended, heavy soil and gross filth should be removed followed by thorough cleaning of all surfaces prior to disinfection.

USE DILUTIONS

1. **OFFICIAL DISINFECTION PROGRAMS:** Tuberculocidal at 1 gallon to 100 gallons water (4 oz. to 3 gallons water). Permitted for use by the Animal Health Program, Veterinary Service, Animal and Plant Health Service, USDA, in Official Disinfection Programs involving domestic animal housing and transportation facilities. For use in Official Disinfection Programs, preclean surfaces and apply a disinfecting solution of 1 to 2 gallons per 100 gallons water (4 to 8 oz. per 3 gallons water).

2. **FOR NORMAL DISINFECTION.** Use 1 to 2 gallons in 200 gallons of water (2 to 4 oz. per 3 gallons water). Light to moderately soiled surfaces may be cleaned and disinfected in one operation. Preclean heavily soiled surfaces, rinse with water, then apply disinfecting solution.

3. **PREMISES WITH DISEASE HISTORY.** Preclean surfaces, rinse and disinfect with 1 to 2 gallons in 100 gallons of water.

STORAGE AND 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.

METAL CONTAINERS: Triple rinse. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

PLASTIC CONTAINERS: Triple rinse. 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.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Highly corrosive. Causes skin and eye damage. May be fatal if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Avoid breathing spray mist. Avoid contamination of food.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not discharge into lakes, streams, ponds, or public water, unless in accordance with an NPDES Permit. For guidance, contact the regional office of EPA.

PHYSICAL AND CHEMICAL HAZARDS: Contains alcohol. Do not use or store near heat, fire or open flame. Keep container closed except when in use.

PRACTICAL TREATMENT: Immediately on contact, flush eyes or skin with plenty of water for at least 15 minutes. Call a physician for eyes. Remove and wash contaminated clothing before reuse.

If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution, or, if these are not available, water. Contact a physician immediately. Avoid alcohol.

ACCEPTED
with COMMENTS
In EPA Letter Dated:

EPA Reg. No. 5185-334
EPA Est. No. 5185-6a-2

SEP 28 1988

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, and the pesticide
registration provisions of EPA Reg. No.

5185-334