JAN 22 2001

West Agro, Inc. 501 Santa Fe Kansas City, MO 64105

Attention: Dollie Howser

Regulatory Specialist

Subject:

1

XXX Disinfectant

EPA Registration Number 4959-15

Your Submission Dated January 17, 2001

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to revise your label per PR Notice 2000-3 will be acceptable provided that you make the labeling changes listed below before you release this product for shipment bearing the amended label.

- Under the "First Aid Statement" revise the "If Swallowed" to read: 1.
 - Call poison control center or doctor immediately for treatment advice. 0
 - Have person sip a glass of water if able to swallow.
 - Do not induce vomiting unless told to do so by the poison control center or o doctor.
 - Do not give anything by mouth to an unconscious person. 0
- Under the "Environmental Hazards Statement" revise the first sentence to read: 2. This product is toxic to fish and aquatic organisms. Delete the second sentence "Keep out of lakes, ponds or streams".
- The "Company Name and Address" must be listed on the label. 3.
- 4. Delete the number "0006-1100", it has no relevance to EPA registered products.

A stamped copy is enclosed for your records. Submit one copy of the final printed label before you release the product for shipment bearing the amended label.

| CONCURRENCES | | | | | | | | | |
|--------------|----------------|---|---------------------------|--|---|--|--|--|--|
| SYMBOL | 75100 | · | | | | | | | |
| SURNAME) | لبولي | | | | *************************************** | | | | |
| DATE | 1/22/01 | | | | | | | | |
| EPA Form | 1320-1A (1/90) | | Printed on Recycled Paper | ······································ | OFFICIAL FILE COPY | | | | |

If you have any questions concerning this letter, please contact Delores Williams at (703) 308-6372.

Sincerely,

Robert S. Brennis

Product Manager (32)

Regulatory Management Branch II Antimicrobials Division (7510C)

FOR INDUSTRIAL, I STITUTIONAL AND AGRICULTRAL USE

XXX DISINFECTANT

Authorized by USDA for use in federally inspected meat, poultry and egg processing plants.

CONCENTRATED BROAD SPECTRUM IODOPHOR FOR USE AS A ONE-STEP CLEANER-DISINFECTANT AND NO-RINSE SANITIZER IN:

◆Veterinary Clinics ◆Poultry & Livestock Drinking Water ◆Sanitizing Commercial Eggs ◆Egg Processing Plants ◆Dairy & Poultry Farms ◆Meat & Poultry Plants ◆Food \$\mathbb{P}^2\tau cessing Plants ◆Kennels, Pet Shops & Zoos ◆Hand Sanitizing in Food Plants ◆Animal Handling Facilities

Pruberculocide, virucide*, bactericide, fungicide, deodorizer

Used as directed XXX Disinfectant is effective in hard water (up to 400 ppm as CaCO₃) and in 5% organic serum load against the following viruses, becteria and pathogenic fungl: Polio 1*, Vaccinia*, Herpes Simplex Type 1*, Influenza A2/Japan 305*, and Carine Parvovirus*; bectericidal against Salmonella cholerasuis, Staphylococcus eureus, Pseudomonas aeruginosa, and E. Coff; is fungicidal against Trichophyton mentagrophytes (the athlete's foot fungus).

On pre-cleaned food contact surfaces XXX Disinfectant is effective against Salmonella cholerasuis, Listeria monocytogenes and Escherichia coli, 0157:H7, Hemorrhagic.

Used as directed XXX Disinfectant is tuberculocidal when used in hard water (up to 400 ppm as CaCO₂) on precisened surfaces at 20°C for a contact time of 10 minutes. Prepare a solution of 3 ounces XXX Disinfectant to 5 gallons water (provides 75 ppm titratable indine).

ACTIVE INGREDIENT:

| lodina* | | <u>.</u> | | | | | | | | | | | . 1.75% |
|---|-----|------------------|--|--|--|--|------|--|--|--|--|---|---------|
| INERT INGREDIEN | TS: | . . . | | | | | | | | | | _ | 98,25% |
| Total | | | | | | | | | | | | - | 100.00% |
| *Crom alaba ta consighe and come a hydroxyrotylographylogical to dise complex | | | | | | | | | | | | | |

PRECAUTIONARY STATEMENTS: Hazard to humans and domestic animals

KEEP OUT OF THE REACH OF CHILDREN DANGER:

CORROSIVE. Causes irreversible eye demage. Harmful if awallowed. Do not get in eyes or on clothing. Avoid contact with skin. Wear goggles or face shield, Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Keep out of lakes, pends or streams. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge offluent containing this product into lakes, streams, pends, estuaries, oceans or better water 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 offluent containing this product to sewer systems without a praylously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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☐ EPA Reg. No. 4959-15 ☐ EPA Est. No.

JAN 22 2001

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FRST AID

FIN EXES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after first 5 munites. Then continue rineing. Call a Polson Control Center or doctor for treatment advise.

F CN SIGN: Take off contaminated clothing. Rinse skin Immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advise.

F SWALLOWED: Call a Poison Control Center or doctor for treatment advise. Do not induce vomiting. Drink promptly a large quantity of milk, egg whites, geletin colution, or if these are not available, drink large quantities of water. Avoid alcohol.

FRIMED: Move person to fresh air. If person is not breathing, call 11 or ambulance, then give artifical respiration, perferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for treatment advise.

NOTE TO PHYSICIAN: Probable mucosal damagemay contraindicate the use of gastic lavage.

Measuras against circulatory shock, respiratory depression and convulsions may be needed.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a menner inconsistent with its labeling. Not for Residential Use.

The color of an XXX Disinfectant solution is proportional to the titratable iodine concentration. Prepare a fresh solution daily, or when there is a noticeable change in its rich amber color, or more often if the solution becomes diluted or soiled.

ONE-STEP CLEANING AND DISINFECTING:

PRIOR TO USE in Veterinary Clinics, Animal Handling Facilities, Farm Premises, Kennels, Pet Shops and Zoos: Remove all animals and feeds from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and all surfaces to be treated. Empty all troughs, racks and other feeding and watering appliances. Then proceed as directed below.

TO CLEAN AND DISINFECT: Before applying disinfecting solution, food products and packaging materials must be removed from the room or carefully protected. Remove heavy soil deposits before applying the disinfecting solution. Using a solution of 3 ounces XXX Disinfectant per 5 gallons of warm water (68°F, 20°C or warmer), immerse objects in disinfecting solution, or apply solution with a map, sponge or brush. Where appropriate, use a mechanical sprayer to produce coarse spray. Allow a 10 minute contact time with disinfecting solution. For efficacy against Canine Parvovirus, allow a 120 minute contact time; surface must remain wet. All food contact surfaces must be rinsed with potable water before rause. Floors, walls and all other non-food contact surfaces may drain dry without rinsing.

DIRECTIONS FOR USE (Cont.)

<u>NOTE:</u> When mixing XXX Disinfectant with cold water (as low as 41°F, 5°C), increase use to 6 oz. per 5 gallons water.

**DEFORE REHOUSING ANIMALS: Ventilate buildings, vehicles and other closed inpaces. Do not house animals or use equipment until treatment absorbs, sets or a SHOE BATH: Routine use of shoe bath sanitizers helps reduce the spread of disease causing organisms between poultry houses, farrowing houses, hog barns and other livestock buildings. Use 3 ounces of XXX Disinfectant per 1 gallon of water. Place stanitizing solution in shallow plastic or stainless steel pans inside all entrances to boultry and livestock buildings. Scrape shoes outside doorway and stand in shoe sath for 30 seconds before entering building. Replace shoe bath daily or more often figuration becomes soiled.

CLEANING MILKING EQUIPMENT AND BULK TANKS: Immediately after milking, flush milking equipment and utensils with lukewarm (100°F, 38°C) water to wash out all milk. Take apart milking machines and immerse air hoses, inflations, metal parts (except pulsator) and utensils in a solution containing 1 ounce of XXX Disinfectant per 5 gallons of water. Brush all parts thoroughly. Drain completely, rinse with water and allow to air dry. After emptying bulk tanks, flush tanks thoroughly with 100°F (38°C) water to wash out all milk. Brush tanks thoroughly with a solution containing 1 ounce XXX Disinfectant per 5 gallons of water. Allow wash solution to drain, rinse with water and air dry.

SANITIZING MILKING MACHINES AND BULK TANKS: Before each milking, flush assembled milking machines and empty bulk tanks with a solution containing 1 cunce of XXX Disinfectant per 5 gallons of water. Allow a 1 minute contact time. Drain thoroughly and air dry before use.

REMOVAL OF MILKSTONE AND HARD WATER DEPOSITS: Yellow color may appear on equipment after the first use of XXX Disinfectant. This may indicate the presence of milkstone or hard water deposits. Remove these deposits by applying a solution containing equal parts of XXX Disinfectant and lukewarm water. Wait 2-3 minutes, brush and then rinse with potable water. Daily use of XXX Disinfectant will help prevent the formation of milkstone and hard water deposits.

SANITIZING POULTRY AND LIVESTOCK DRINKING WATER: Add 1 ounce of XXX Disinfectant per 10 gallons of drinking water. Regular use of this product in drinking water reduces the buildup of slime and mineral deposits in watering equipment. Do with not use this product together with other water treatments such as medications.

SANITIZING PREVIOUSLY CLEANED FOOD CONTACT SURFACES: Sanitize previously cleaned and rinsed hard, non-porous surfaces such as glass, metal, plastic and porcelain with a solution containing 1 ounce of XXX Disinfectant per 5 gallons of water. Immerse equipment with sanitizing solution and allow 1 minute of contact time. Drain solution from equipment; do not rinse. XXX Disinfectant used at 1 ounce per 5 gallons of water contains 25 ppm titratable iodine and does not require a final rinse with potable water in accordance with Federal Food Additive Regulation 178.1010.

Regulation 178.1010.

NET CONTENTS:

LOT NO:

Made In USA

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0006-1100

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SANITIZING GLASSES, DICTARE, POTS, PANS, AND UTENSILS IN FOOD SERVICE OPERATIONS:

- Pre-flush or pre-scrape equipment and utensils. If needed, pre-soak to remove gross food particles and soil.
- Wash equipment and utensils in lukewarm water that contains an adequate amount of a good detergent or cleaner. Keep this water clean by frequent changing.
- 3. Rinse equipment and utensils free of wash water prior to sanitization.
- 4. Sanitize equipment and utensils by immersing them in a solution of 1 cunce XXX Disinfectant per 5 gallons of lukewarm water (provides 25 ppm titratable indine). Allow one minute contact time (or longer if required by local sanitation codes). Fresh solution should be prepared deity or more often if the solution becomes diluted or solled. Use an approved indine test kit to check for proper concentrations.
- After required contact time of one minute or more, allow equipment and utensile to drain and then air dry. Do not rinse before use.

SANITIZING FOOD-GRADE EGG SHELLS: Coarse apray previously cleaned food-grade egg shells with a solution containing 1 ounce of XXX Disinfectant per 5 gallons of water. Solution temperature should be warmer than the eggs, but not to exceed 130°F (53°C). Wet aggs thoroughly for 1 minute and allow to drain. A final potable water rinse is not required. Eggs should be reasonably dry before casing or breaking. Do not reuse solution to earlitize eggs.

HAND SANITIZING: Thoroughly wash and rinse hands before sanitizing. Dip or rinse hands in a solution containing 1 ounce of XXX Disinfectant per 5 gallons of water. XXX Disinfectant may be injected directly into wash or rinse water at a rate of 1 ounce per 5 gallons of water. A final potable water rinse is not required.

DEODORIZING: XXX Disinfectant destroys many odors as it sanitizes and disinfects. For general deodorant applications (garbage palls, refuse containers, etc.), swab surface to be treated with a solution containing 1 ounce of XXX Disinfectant per gallon of water. Allow treated surface to drain and sir dry.

USE DILUTION TABLE

| XXX DISINFECTANT/WATER= | TITRATABLE IODINE | | | | | | | |
|-------------------------|-------------------|--|--|--|--|--|--|--|
| 1 oz to 10 gal. | 12.5 ppm | | | | | | | |
| 1 oz to 5 gai. | 25 ppm | | | | | | | |
| 3 oz to 5 gal. | 75 ppm | | | | | | | |
| 1 oz to 1 gal. | 125 ppm | | | | | | | |
| 6 oz to 5 gal. | 150 p p an | | | | | | | |

STORAGE AND DISPOSAL

Keep container closed when not in use. Do not store below 25°F or above 100°F for extended periods.

PROHIBITIONS: Do not contaminate water, food or feed by storage or disposal. Open demoing is prohibited.

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 incinerate, or, if allowed by State and local authorities, burn container. If burned, stay out of smoke.