11900 -15

DEC 1 3 1990

West Agro, Inc. 11100 North Congress Avenue Kansas City, MO 64153

Attention: Richard Beach

Regulatory Specialist

Gentlemen:

Subject: XXX Disinfectant

EPA Registration No. 4959-15

Your Amendment Dated August 31, 1990

This is in response to your request to amend the registration of the subject product to include additional claims of effectiveness and labeling revisions.

The submitted data appear adequate to support efficacy of the product as a bactericide against Pseudomonas aeruginosa at a 1:213 dilution in synthetic hard water, 400 parts per million (ppm) as CaCO3 on hard nonporous and food contact surfaces.

The submitted data appear adequate to support efficacy of the product as a fungicide against <u>Trichophyton mentagrophytes</u> at a 1:213 dilution in synthetic hard water, 400 ppm as CaCO₃ on hard nonporous and food contact surfaces.

The submitted letter from the Food and Drug Administration satisfactorily fulfills our requirement in regard to the acceptability of the hand dipping claim for this product.

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you:

- 1. Make the following labeling revision before you release the product for shipment bearing the amended labeling:
 - Include the company's name and address.

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2. Submit five (5) copies of the finished labeling before you release the product for shipment.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

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,

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Walter C. Francis Acting Product Manager (32) Antimicrobial Program Branch Registration Division (H7505C)

Enclosure

FOR INDUSTRIAL "INSTITUTIONAL AND AGRICAL TURAL 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 SANITY.

• Veterinary Clinics • Poultry & Livestock Drinking Water • Sanitizing Commercial Eggs • Egg Processing Plants • Dairy & Poultry Plants • Food Processing Plants • Kennels, Pet Shops & Zoos • Hand Sanitizing in Food Plants • Animal Handling Facilities

Used as directed XXX DISINFECTANT is effective against Salmonella cholerasuls, Staphylococcus aureus, Pseudomonas aeruginose, Mycobacterium tuberculosis, and pathogenic fungi.

ACTIVE INGREDIENTS:

 Titratable lodine*
 1.75%

 INERT INGREDIENTS:
 98.25%

 Total
 100.00%

PRECAUTIONARY STATEMENTS: HAZARD TO HUMANS AND DOMESTIC ANIMALS

KEEP OUT OF THE REACH OF CHILDREN DANGER:

CORROSIVE. Causes irreversible eye damage. Harmful if swallowed. 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 into lakes, streams, ponds or public waters unless in accordance with a NPDES permit. For guidance, contact the regional office of EPA.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. If swallowed, drink promptly plarge quantity of water. Do not induce vomiting. Avoid alcohol. Get medical attention. Remove and wash all contaminated clothing before reuse.

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

EPA Reg. No. 4959-15-

EPA Est. No.

-State-01

ACCEPTED
with COMMENTS
in EPA Letter Dated:

Sold By

DEC 1 3 1990

company logo

company name

address

Under the Fe for al Insecticité, Pungieide, and Rudenheide Act an amended, for the pesticide required under EPA Reg. No.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a labeling.

Not for Residential Use.

The color of an XXX DISINFECTANT solutio titratable iodine concentration. Prepare a frest there is a noticeable change in its rich amber consolution becomes diluted or soiled. Used as direct is effective in hard water (up to 400 ppm as Coserum load against listed bacteria and pathogen

ONE-STEP CLEANING AND DISINFECTING:

PRIOR TO USE in Veterinary Clinics, Animal Premises, Kennels, Pet Shops and Zoos: Remoter from premises, vehicles and enclosures. Remove floors, walls and all surfaces to be treated. Empother feeding and watering appliances. Then premises are presented to the premise of the p

TO CLEAN AND DISINFECT: Before applying of products and packaging materials must be rerearefully protected. Remove heavy soil depodisinfecting solution. Using a solution of 3 our per 5 gallons of warm water (68°F, 20°C or wardisinfecting solution, or apply solution with a Where appropriate, use a mechanical sprayer. A time with disinfecting solution. All food contact with potable water before reuse. Floors, wall contact surfaces may drain dry without rinsing.

NOTE: When mixing XXX DISINFECTANT wir 41°F, 5°C), increase use to 6 oz. per 5 gallons

BEFORE REHOUSING ANIMALS: Ventilate buil closed spaces. Do not house animals or use absorbs, sets or dries. Thoroughly rinse all treatroughs, automatic feeders, fountains and wat before reuse.

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^{*}From alphd-(p-nonylphenyl)-omega-hydroxypoly(oxyethylene)-lodine complex

DIRECTIONS FOR USE (Cont.)

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 sanitizing solution in shallow plastic or stainless steel pans inside all entrances to poultry and livestock buildings. Scrape shoes outside doorway and stand in shoe bath for 30 seconds before entering building. Replace shoe bath daily or more often if solution 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 ounce 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 ½ ounce of XXX DISINFECTANT per 10 gallons of drinking water. Regular use in drinking water reduces slime buildup and mineral deposits in watering equipment. Discontinue sanitizer use when treating animals with other water medicants.

SANITIZING PREVIOUSLY CLEANED FOOD CONTACT SURFACES: Sanitize previously cleaned and rinsed hard, non-porus surfaces such as glass, metal, plastic and porcelain with a solution containing 1 ounce of XXX DISINFECTANT per 5 gallons of water. Spray or 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 titrafable iodine and does not require. In a final rinse with potable water in accordance with Federal Food Additive Regulation 178.1010.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 1 3 1990

Under the Federal Insecticide, Funguede, and Rudenticide Act as amended, for the pesticide regassered under EPA Rus Na. SANITIZING FOOD-GrADE EGG SHELLS: Spray previously cleaned food-grade egg shells with a solution containing 1 ounce of XXX DISINFECTART per 5 gallons of water. Solution temperature should be warmer than the eggs, but not to exceed 130°F (53°C). Wet eggs thoroughly for 1 minute and allow to drain. A final potable water rinse is required only if eggs are to be immediately broken for processing into egg products. Eggs should be reasonably dry before casing or breaking. Do out reuse solution to sanitize 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 pails, refuse containers, etc.), swab or spray surface to be treated with a solution containing 1 ounce of XXX DISINFECTANT per gallon of water. Allow treated surface to drain and air dry.

USE DILUTION TABLE

XXX DISINFECTANT/WATER=	TITRATABLE IODINE
1 oz to 10 gal.	12.5 ppm
1 oz to 5 gał.	25 ppm
3 oz to 5 gal.	75 ppm
1 oz to 1 gal.	125 ppm
6 oz to 5 gal.	150 ppm

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 dumping 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.

NET CONTENTS:

LOT NO:

Mede in USA

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