

Mr. Richard Beach
WestAgro, Inc.
11100 N. Congress Ave.
Kansas City, MO 64153-1222

SUBJECT: XXX Disinfectant
EPA Registration No. 4959-15
ZZZ Disinfectant
EPA Registration No. 4959-16
Application Dated April 2, 1993

Dear Mr. Beach:

This is in response to your amendment to include additional bactericidal and virucidal claims on the labeling for the referenced products. The following comments apply.

The submitted data are acceptable to support effectiveness of these products as a disinfectant against Escherichia coli ATCC 8739 and as a virucide against Herpes Simplex Type 1, Influenza A2/Japan/305, Poliovirus 1 (Chat strain), Vaccinia virus and Cyanine Parvovirus at a 1:213 dilution on hard, non-porous surfaces in the presence of 5% blood serum and 400 ppm CaCO₃ hard water for a contact time of 10 minutes at 20⁰ C.

The submitted data are also acceptable to support effectiveness of the product as a virucide against Canine Parvovirus at a 1:213 dilution on hard, non-porous surfaces in the presence of 5% blood serum and 400ppm CaCO₃ hard water for a contact time of 2 hours at 20⁰ C.

The submitted data by the AOAC Available Chlorine Germicidal Equivalent Concentration Test are also acceptable to support effectiveness of these products as sanitizing rinses for previously cleaned food contact surfaces against Listeria monocytogenes at the recommended use dilution of 1:640 (25 ppm titratable iodine) for a contact time of 1 minute at 20⁰ C.

LABELING

See the enclosed efficacy reviews for the labeling deficiencies. Submit 5 draft copies of each revised label incorporating the changes noted.

If you have any further questions, please contact Ms. Barbara Pringle at (703)305-6484.

Sincerely,



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

FOR INDUSTRIAL, INSTITUTIONAL AND AGRICULTURAL 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
 Processing Plants •Kennels, Pet Shops & Zoos •Hand Sanitizing in Food Plants •Animal Handling Facilities

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner not intended. **Not for Residential Use.**

The color of an XXX Disinfectant solution is proportional to concentration. Prepare a fresh solution daily, or weekly in its rich amber color, or more often if the solution is used.

ONE-STEP CLEANING AND DISINFECTING:
PRIOR TO USE in Veterinary Clinics, Animal Handling Facilities, Kennels, Pet Shops and Zoos: Remove all animal waste, vehicles and enclosures. Remove all litter and manure from surfaces to be treated. Empty all troughs, racks and appliances. Then proceed as directed below.

TO CLEAN AND DISINFECT: Before applying disinfectant, all food and packaging materials must be removed from the area. Remove heavy soil deposits before applying the disinfectant solution of 3 ounces XXX Disinfectant per 5 gallons of water (warmer), immerse objects in disinfecting solution for 10 minutes with sponge or brush. Where appropriate, use a mechanical contact time with disinfecting solution. All food and water must be removed with potable water before reuse. Floors, walls and surfaces may drain dry without rinsing.

NOTE: When mixing XXX Disinfectant with colorless water, increase use to 6 oz. per 5 gallons water.

BEFORE REHOUSING ANIMALS: Ventilate buildings and spaces. Do not house animals or use equipment until surfaces are dry. Thoroughly rinse all treated feed racks, manure troughs and waterers with potable water before reuse.

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 EPA Est. No.

TUBERCULOCIDE, 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, bacteria and pathogenic fungi: Polio 1, Vaccinia, Herpes Simplex Type 1, influenza A₂, and Canine Parvovirus; bactericidal against *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *E. Coli*; is fungicidal against *Trichophyton mentagrophytes* (the athlete's foot fungus).

XXX Disinfectant is effective against *Listeria monocytogenes* on pre-cleaned food contact surfaces.

Used as directed XXX Disinfectant is tuberculocidal when used in hard water (up to 400 ppm as CaCO₃) and on precleaned surfaces. Prepare a solution of 3 ounces XXX Disinfectant to 5 gallons water (provides 75 ppm titratable iodine).

ACTIVE INGREDIENTS:	
Iodine*	1.75%
INERT INGREDIENTS:	
	98.25%
Total	100.00%

*From alpha-(p-nonylphenyl)-omega-hydroxypoly(oxyethylene)-iodine complex

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, ponds 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 a large 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 may be needed.

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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 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 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. 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 titratable iodine and does not require a final rinse with potable water in accordance with Federal Food Additive Regulation 178.1010.

NET CONTENTS:

LOT NO:

Made in USA

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SANITIZING GLASS, DISHWARE, POTS, PANS, AND UTENSILS IN FOOD SERVICE OPERATIONS:

1. Pre-flush or pre-scrape equipment and utensils. If needed, pre-soak to remove gross food particles and soil.
2. 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 containing 1 ounce **XXX Disinfectant** per 1 gallon of lukewarm water (provides 25 ppm titratable iodine). Allow the 1 minute contact time (or longer if required by local sanitation codes). Use water as needed to maintain a minimum of 25 ppm iodine, replacing at least once daily. Use an approved iodine test kit to check for proper concentrations.
5. After required contact time of one minute or more, allow equipment and utensils to air dry. Do not rinse before use.

SANITIZING FOOD-GRADE EGG SHELLS: Spray 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 (54°C). Wet eggs 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 on other eggs.

HAND SANITIZING: Thoroughly wash and rinse hands before sanitizing. Then immerse 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 surfaces. For general deodorant applications (garbage pails, refuse containers, etc.), spray the surface to be treated with a solution containing 1 ounce of **XXX Disinfectant** per 5 gallons of water. Allow treated surface to drain and air dry.

USE DILUTION TABLE

<u>XXX DISINFECTANT/WATER =</u>	<u>TITRATABLE IODINE</u>
1 oz to 10 gal.	12.5 ppm
1 oz to 5 gal.	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 (7°C) or above 100°F (38°C) 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 to recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by State and local authorities, burn container. If burned, do not breathe smoke.

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