

JUL 1 1994

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

SUBJECT: YYY Disinfectant  
EPA Registration No. 4959-34  
Application Dated April 2, 1993

Dear Mr. Beach:

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

The submitted data are acceptable to support effectiveness of this product as a disinfectant against Escherichia coli ATCC 8739 and as a virucide against Herpes Simplex Type 1, InfluenzaA2/Japan/305, Poliovirus 1 (Chat strain), Vaccinia viruses at 1:42 dilution on hard, non-porous surfaces in the presence of 5% blood serum and 400 ppm CaCO<sub>3</sub> hard water for a contact time of 10 minutes at 20° C.

The submitted data are also acceptable to support effectiveness of the product as a virucide against Canine Parvovirus at a 1:42 dilution on hard, non-porous surfaces in the presence of 5% blood serum and 400ppm CaCO<sub>3</sub> hard water for a contact time of 2 hours at 20° C.

The submitted data by the AOAC Available Chlorine Germicidal Equivalent Concentration Test are also acceptable to support effectiveness of this product as a sanitizing rinse for previously cleaned food contact surfaces against Listeria monocytogenes at the recommended use dilution of 1:128 (25 ppm titratable iodine) for a contact time of 1 minute at 20° C.

#### LABELING

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

#### CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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

# YYY DISINFECTANT

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  
•Food Processing Plants •Kennels, Pet Shops & Zoos •Hand Sanitizing in Food Plants •Animal Handling Facilities •Hospitals and Clinics  
•Dental Offices •Schools and Institutions •Nursing Homes •Kitchens and Lunch Rooms •Restrooms

TUBERCULOCIDE, VIRUCIDE, BACTERICIDE, FUNGICIDE, DEODORIZER  
Meets OSHA's Bloodborne Pathogens Act requirement.

Used as directed, YYY DISINFECTANT is effective in hard water (up to 400 ppm  $\text{CaCO}_3$ ) and in 5% organic serum load against the following viruses, bacteria and pathogenic fungi: Polio 1, Vaccinia, Herpes Simplex Type 1, Influenza A<sub>2</sub>, and Canine Parvovirus; is bactericidal against *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *E. Coli*; fungicidal against *Trichophyton mentagrophytes* (the athlete's foot fungus).

YYY DISINFECTANT is effective against *Listeria monocytogenes* on pre-cleaned food contact surfaces.

Used on pre-cleaned environmental surfaces in hard water (up to 400 ppm  $\text{CaCO}_3$ ), YYY DISINFECTANT is effective against Mycobacterium tuberculosis.

Used in hard water (up to 400 ppm  $\text{CaCO}_3$ ), YYY DISINFECTANT is effective against the *HIV-1 Virus* on pre-cleaned environmental surfaces and objects previously soiled with blood or other body fluids.

#### ACTIVE INGREDIENT:

Iodine\* ..... 0.35%

INERT INGREDIENTS: ..... 99.65%

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 at least 15 minutes. For eyes, call a physician promptly a large quantity of water. Do not induce vomiting. Get medical attention. Remove and wash all contaminated clothing.

NOTE TO PHYSICIAN: Probable mucosal damage may require use of gastric lavage. Measures against circulatory depression and convulsions may be needed.

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EPA Est. No. \_\_\_\_-State-01

#### STORAGE AND DISPOSAL

Keep container closed when not in use. Do not store at 100°F for extended periods.

PROHIBITIONS: Do not contaminate water, food or feed. Open dumping is prohibited.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Follow Federal law for disposal of excess pesticide, spray mixture or other container. If these wastes cannot be disposed of by other means, contact your State Pesticide or Hazardous Waste Agency, or the Hazardous Waste representative of the Regional Office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent) and recycle or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authority, by other means. If burned, stay out of smoke.

#### DIRECTIONS FOR USE:

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

The color of a YYY DISINFECTANT solution is proportional to the iodine concentration. Prepare a fresh solution daily when a noticeable change in its rich amber color, or when it becomes diluted or soiled.

Sold By

company logo

company name

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## AGRICULTURAL

### **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 3 ounce solution of **YYY DISINFECTANT** per 1 gallon of warm water (68°F, 20°C or warmer), immerse objects in disinfecting solution, or apply solution with mop, sponge or brush. Where appropriate, use a mechanical sprayer. Allow a 10 minute contact time with disinfecting solution. All food contact surfaces must be rinsed with potable water before reuse. Floors, walls and all other non-food contact surfaces may drain dry without rinsing.

**NOTE:** When mixing **YYY DISINFECTANT** with cold water (as low as 41°F, 5°C), increase use to 6 oz. per 1 gallon water.

**BEFORE REHOUSING ANIMALS:** Ventilate buildings, vehicles and other closed spaces. Do not house animals or use equipment until treatment absorbs, sets or dries. Thoroughly rinse all treated feed racks, mangers, troughs, automatic feeders, fountains and waterers with potable water before reuse.

**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 15 ounces of **YYY 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 **YYY DISINFECTANT** per 1 gallon 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 **YYY DISINFECTANT** per 1 gallon 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 **YYY DISINFECTANT** per 1 gallon of water. Allow a 1 minute contact time. Drain thoroughly and air dry before use.

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**REMOVAL OF MILKSTONE AND HARD WATER DEPOSITS:** Yellow color may appear on equipment after the first use of **YYY DISINFECTANT**. This may indicate the presence of milkstone or hard water deposits. Remove these deposits by applying **YYY DISINFECTANT** in its concentrated form. Wait 2-3 minutes, brush and then rinse with potable water. Daily use of **YYY DISINFECTANT** will help prevent the formation of milkstone and hard water deposits.

**SANITIZING POULTRY AND LIVESTOCK DRINKING WATER:** Add 1 ounce of **YYY DISINFECTANT** per 2 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 **YYY DISINFECTANT** per 1 gallon of water. Spray or immerse equipment with sanitizing solution and allow 1 minute of contact time. Drain solution from equipment; do not rinse. **YYY DISINFECTANT** used at 1 ounce per 1 gallon 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.

**SANITIZING FOOD-GRADE EGG SHELLS:** Spray previously cleaned food-grade egg shells with a solution containing 1 ounce of **YYY DISINFECTANT** per 1 gallon 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 not required. Eggs should be reasonably dry before casing or breaking. Do not 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 **YYY DISINFECTANT** per 1 gallon of water. **YYY DISINFECTANT** may be injected directly into wash or rinse water at a rate of 1 ounce per 1 gallon of water. A final potable water rinse is not required.

**DEODORIZING:** **YYY 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 5 ounces of **YYY DISINFECTANT** per gallon of water. Allow treated surface to drain and air dry.

### **USE DILUTION TABLE**

<b>YYY DISINFECTANT/WATER =</b>	<b>TITRATABLE IODINE</b>	
1 oz to 2 gal.	12.5	ppm
1 oz to 1 gal.	25	ppm
3 oz to 1 gal.	75	ppm
5 oz to 1 gal.	125	ppm
6 oz to 1 gal.	150	ppm

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**ONE-STEP CLEANING AND DISINFECTING:**

This product may be used to clean and disinfect operating areas, patient rooms, floors, walls, counter tops, rest rooms, shower areas, refuse containers, bed frames, morgues, laboratories, cafeterias, commercial freezers, animal rooms, cages and other hard, non-porous surfaces. 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 of **YYY DISINFECTANT** per 1 gallon of warm water (68°F, 20°C or warmer), immerse objects in disinfecting solution, or apply with a mop, sponge or brush. Where appropriate, use a mechanical sprayer. Allow a 10 minute contact time with disinfecting solution. All food contact surfaces must be rinsed with potable water before reuse. Floors, walls and all other non-food contact surfaces may drain dry without rinsing.

**NOTE:** When using cold water temperatures (as low as 41°F, 5°C) use a solution containing 6 ounces of **YYY DISINFECTANT** per 1 gallon of water.

To disinfect surgical and medical instruments, tubing, catheters, thermometers and rubber gloves follow the special instructions listed below.

**KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS** in health care settings or other settings in which there is an expected likelihood of soiling or inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

**SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES AND OBJECTS PREVIOUSLY SOILED WITH BLOOD OR OTHER BODY FLUIDS:**

**PERSONAL PROTECTION:** While handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings (goggles or glasses).

**CLEANING PROCEDURE:** Before applying disinfecting solution thoroughly clean blood and other body fluids from hard surfaces, interior and exterior surfaces of instruments and objects to be decontaminated. Thoroughly wet hard surfaces with a solution containing 3 ounces of **YYY DISINFECTANT** per 1 gallon of water. Completely immerse small objects and instruments in the disinfecting solution. Flush and fill tubing, catheters and the lumen of hollow instruments with the disinfecting solution; avoid entrapment of air bubbles. Allow at least 10 minutes of contact time.

**DISPOSAL OF INFECTIOUS MATERIAL:** Blood and other body fluids should be autoclaved and disposed of according to Federal, State and Local regulations for infectious waste disposal.

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**TO CLEAN AND DISINFECT TOILET BOWLS AND URINALS:** Flush toilet. Add 5 ounces of **YYY DISINFECTANT** directly to water in toilet bowl. Brush to cover all bowl surfaces including under the rim. Allow disinfectant to remain for at least 10 minutes. Flush toilet. Rinse metal parts with water after disinfecting to prevent corrosion.

**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 **YYY DISINFECTANT** per 1 gallon of water. Spray or immerse equipment with sanitizing solution and allow 1 minute contact time. Drain solution from equipment; do not rinse. **YYY DISINFECTANT** used at 1 ounce per 1 gallon 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.

**HAND SANITIZING IN FOOD PROCESSING PLANTS:** Thoroughly wash and rinse hands before sanitizing. Dip or rinse hands in a solution containing 1 ounce of **YYY DISINFECTANT** per 1 gallon of water. **YYY DISINFECTANT** may be injected directly into wash or rinse water at a rate of 1 ounce per 1 gallon of water. A final potable water rinse is not required.

**SANITIZING GLASSES, 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 of 1 ounce **YYY Disinfectant** per 1 gallon of lukewarm water (provides 25 ppm titratable iodine). Allow one minute contact time (or longer if required by local sanitation codes). Change water as needed to maintain a minimum of 25 ppm iodine, replacing at least once per day. 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.

**USE DILUTION TABLE**

<b>YYY DISINFECTANT/ WATER</b>	<b>TITRATABLE IODINE</b>
1 oz to 1 gallon water	25 ppm
3 oz to 1 gallon water	75 ppm
6 oz to 1 gallon water	150 ppm

**NET CONTENTS:**

**LOT NO:**

Made in USA

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