

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 31 1994

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 400pppm 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.

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)

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FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY
ZZZ DISINFECTANT

CONCENTRATED BROAD SPECTRUM IODOPHOR FOR USE AS A ONE-STEP CLEANER-DISINFECTANT AND NO-RINSE SANITIZER
Hospitals and Clinics Food Processing Plants Dental Offices Hand Sanitizing in Food Plants Schools and Institutions
Nursing Homes Kitchens and Lunch Rooms Restrooms

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

Used as directed, ZZZ DISINFECTANT is effective in hard water (up to 400 ppm CaCO₃) and in 5% organic serum load against the following viruses, bacteria and pathogenic fungi: Polio 1, Vaccinia, Herpes Simplex Type 1, and Influenza A₂; is bactericidal against *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *E. Coli*; fungicidal against *Trichophyton mentagrophytes* (the athlete's foot fungus).

ZZZ 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 CaCO₃), ZZZ DISINFECTANT is effective against *Mycobacterium tuberculosis*.

Used in hard water (up to 400 ppm CaCO₃), ZZZ 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* 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 and rubber gloves when handling. 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, promptly drink a large quantity of water. Call a physician immediately. Do not induce vomiting. Avoid alcohol. Get medical attention. Remove and wash 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.

EPA Reg. No. 4959-16 EPA Est. No. _____-state-
sold by:

DIRECTIONS FOR USE:

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

The color of a ZZZ DISINFECTANT solution is proportional to its concentration. Prepare a fresh solution daily, or more often if the color changes in its rich amber color, or more often if the solution becomes soiled.

ONE-STEP CLEANING AND DISINFECTING:

This product may be used to clean and disinfect floors, walls, counter tops, rest rooms, shower stalls, door frames, morgues, laboratories, cafeterias, common areas, cages and other hard, non-porous surfaces. Before using on food products and packaging materials must be carefully protected. Remove heavy soil deposits with a detergent solution. Using a solution of 3 ounces ZZZ DISINFECTANT per gallon of water (68°F, 20°C or warmer), immerse objects in solution with a mop, sponge or brush. Where a sprayer is used, allow a 10 minute contact time with contact surfaces must be rinsed with potable water. and all other non-food contact surfaces may drain.

NOTE: When mixing ZZZ DISINFECTANT with cold water, increase use to 6 oz. per 5 gallons water.

To disinfect surgical and medical instruments, tools, and rubber gloves follow the special instructions on the label.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS:

Use on environmental settings in which there is an expected likelihood of contact with surfaces/objects with blood or body fluids, and in which surfaces/objects to be soiled with blood or body fluids can be a source of transmission of human immunodeficiency virus (HIV/AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DISINFECTING HIV-1 ON SURFACES AND OBJECTS PREVIOUSLY SOILED WITH OTHER BODY FLUIDS:

PERSONAL PROTECTION: While handling items previously soiled with blood and other body fluids, use disposable latex gloves, gowns, masks and eye protection.

CLEANING PROCEDURE: Before applying disinfectant to surfaces previously soiled with blood and other body fluids from hard surfaces, instruments and objects to be decontaminated, first clean with a solution containing 3 ounces of ZZZ DISINFECTANT per 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.

TO CLEAN AND DISINFECT TOILET BOWLS AND URINALS: Flush toilet. Add 1 ounce of ZZZ 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 ZZZ DISINFECTANT per 5 gallons of water. Spray or immerse equipment with sanitizing solution and allow 1 minute contact time. Drain solution from equipment; do not rinse. ZZZ 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.

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 ZZZ Disinfectant per 5 gallons 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.

HAND SANITIZING IN FOOD PROCESSING PLANTS: Thoroughly wash and rinse hands before sanitizing. Dip or rinse hands in a solution containing .1 ounce of ZZZ DISINFECTANT per 5 gallons of water. ZZZ 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.

USE DILUTION TABLE

ZZZ DISINFECTANT/ WATER	TITRATABLE IODINE
1 oz to 5 gallons water	25 ppm
3 oz to 5 gallons water	75 ppm
6 oz to 5 gallons water	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.

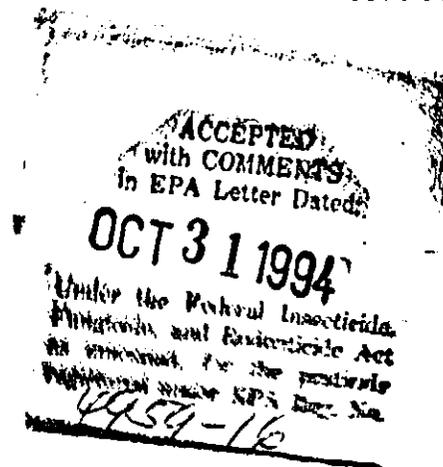
PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the 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.:**

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