

4959-16

5/28/2003

page 1.83

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Ms. Dollie Howser
West Agro, Inc.
11100 N. Congress Avenue
Kansas City, MO 64153

MAY 28 2003

Subject: ZZZ Disinfectant
EPA Registration Number 4959-16
Application Date: 4/14/03
Receipt Date: 4/16/03

Dear Ms. Howser:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

- To update the "first aid" statement in accordance with PR Notice 2001-1

Conditions

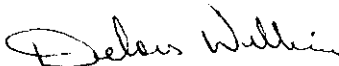
- A "EPA Establishment Number" must be placed on your label.
- On front left panel, place the heading "Precautionary Statements: Hazards to Human and Domestic Animals" above the word "Corrosive".

General Comments

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

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

Sincerely,



for Robert S. Brennis
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

FOR INDUSTRIAL INSTITUTIONAL AND AGRICULTURAL USE

ZZZ DISINFECTANT

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

ACCEPTED
with COMMENTS
EPA Letter Dated:

MAY 28 2003

CONCENTRATED BROAD SPECTRUM IODOPHOR FOR USE AS A ONE-STEP CLEANER-DISINFECTANT AND NO-RINSE SANITIZER IN: Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 4959-16
Hospitals and Clinics Food Processing Plants Dental Offices Hand Sanitizing in Food Plants Schools and Institutions
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 as CaCO_3) and in 5% organic serum load against the following viruses, bacteria and pathogenic fungi: Polio 1*, Vaccinia*, Herpes Simplex Type 1*, and Influenza A2/Japan 305*; 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 CaCO_3), ZZZ Disinfectant is effective against *Mycobacterium tuberculosis* at 20°C for a contact time of 10 minutes.

Used in hard water (up to 400 ppm CaCO_3), ZZZ DISINFECTANT is effective against the HIV-1 Virus* on pre-cleaned environmental surfaces and objects previously soiled with blood or other body fluids. (This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile area of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection).

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. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

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

FIRST AID

If in Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes. Then continue rinsing.• Call a Poison Control Center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a Poison Control Center or doctor immediately for treatment advice.• 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 doctor.• Do not give anything to an unconscious person.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.
If Inhaled	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a Poison Control Center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-424-9300 for emergency treatment information.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage.

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 ZZZ 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:

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 ZZZ

DISINFECTANT per 5 gallons of warm water (68°F, 20°C or warmer). Immerse objects in disinfecting solution, or apply solution with a mop, sponge or cloth. Where appropriate, use a mechanical sprayer to produce coarse spray. Allow a 10 minute contact time with disinfecting solution. All food contact surfaces must be rinsed with potable water before reuse. Floors, walls and other non-food contact surfaces may drain dry without rinsing.

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

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 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 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 objects to be decontaminated. Thoroughly wet hard surfaces with a solution of 3 ounces of **ZZZ DISINFECTANT** per 5 gallons of water. Completely immerse objects in the disinfecting solution; avoid entrapment of air bubbles. Allow at least 10 minutes 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 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, and with a solution containing 1 ounce of **ZZZ DISINFECTANT** per 5 gallons of water. 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 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 cleanser. 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). Fresh solution should be prepared daily or more often if the solution becomes diluted or soiled. 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 drain and then 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 gal.	25 ppm
3 oz to 5 gal.	75 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.

EPA Reg. No. 4959-16

Sold By

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

NET CONTENTS:

LOT NO:

0005-0601

Made in U.S.A.

W
a
W