

February 24, 2006

Joy Seymour
Global Regulatory Specialist
Agent for: West Agro, Inc.
11100 N. Congress Ave.
Kansas City, MO 64153

Subject: **ZZZ** Disinfectant
EPA Registration No. 4959-16
Application Date: November 29, 2005
Receipt Date: November 29, 2005

Dear Ms. Seymour:

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

Proposed Notification

- preservation of HIV claims on the label

Conditions

The current label claim against HIV-1 is acceptable. However, the special instructions on the label are incomplete. They must appear **directly beneath** the HIV-1 claim, and read as follows:

"SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1:

PERSONAL PROTECTION: Clean up should always be done wearing protective latex gloves, gowns, masks, and eye protection. (Specific barrier protection items to be used when handling items soiled with blood or bodily fluids are disposable latex gloves, gowns, masks, or eye coverings.)

CLEANING PROCEDURE: Blood and other body fluids (containing HIV-1) must be thoroughly cleaned from surfaces and objects before application of this product.

DISPOSAL OF INFECTIOUS MATERIALS: Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

CONCURRENCES

SYMBOL	7510C	7510C						
SURNAME	E. Berg	Henson						
DATE	2/24/06	2-24-06						

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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CONTACT TIME: Leave surface wet for 2 minutes with undiluted solution. This contact time will not control other common types of viruses and bacteria listed on this label. To be effective against Hepatitis B virus, a 10 minute contact time is required."

General Comments

A stamped copy of the labeling accepted with conditions is enclosed. Submit one (1) copy of your final printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions of comments concerning this letter, please contact Wanda Henson at 703-308-6345.

Sincerely,

Emily H. Mitchell
Acting 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.

CONCENTRATED BROAD SPECTRUM IODOPHOR FOR USE AS A ONE-STEP CLEANER-DISINFECTANT AND NO-RINSE SANITIZER IN:

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 as 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/Japan 305*, Hepatitis B; 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 as CaCO₃) 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 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. (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 mucus membranes but does not ordinarily penetrate the blood barrier or otherwise enter the 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

INERT INGREDIENTS: 99

Total 100

*From alpha-(p-nonylphenyl)-omega-hydroxy-poly(oxyethyl)-ylene-iodine complex

DANGER:

KEEP OUT OF THE REACH OF CHILDREN

PRECAUTIONARY STATEMENTS: Hazard to humans and domestic animals

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. 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:

- 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:

- 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:

- 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:

- 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 an 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, countertops, rest rooms, shower areas, refuse containers, bed frames, morgues, laboratories, cafeterias, commercial freezers, animal rooms, cages and other hard nonporous 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 all other non-food contact do not require rinsing before reuse.

ACCEPTED
with COMMENTS
EPA Letter Dated:

FEB 24 2006

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 4959-16

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NOTE: When using ZZZ Disinfectant against the following viruses, bacteria and pathogenic fungi: Polio 1*, Vaccinia*, Herpes Simplex Type 1*, and Influenza A2/Japan 305*, *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *E. Coli*, *Trichophyton mentagrophytes*, in a solution of 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 body fluids from hard surfaces, interior and exterior surfaces of objects to be decontaminated. Thoroughly wet hard surfaces with a solution of 3 ounces 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 with a solution containing 1 ounce of ZZZ Disinfectant per 5 gallons of water. Immerse equipment with sanitizing solution and allow 1 minute of 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). 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 adequately drain. 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	
<u>ZZZ DISINFECTANT/WATER=</u>	<u>TITRATABLE IODINE</u>
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

EPA Est. No.

Sold By: West Agro, Inc.
1110 N. Congress Ave.
Kansas City, MO 64153

NET CONTENTS:

LOT NO.:

ACCEPTED
with COMMENTS
EPA Letter Dated:

0005-0105

FEB 24 2006

Made in U.S.A.

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 4959-16

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