

4459-16

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

09-12-2011

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 12 2011

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Tammy Wright
Regulatory Specialist
West Agro, Inc.
11100 N. Congress Ave.
Kansas City, MO 64153

Subject: ZZZ Disinfectant
EPA Reg. No. 4959-16
Application Dated: August 10, 2011
Receipt Date: August 17, 2011

Dear Ms. Wright:

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9 is acceptable.

Proposed Notification:

- Revised Container Disposal Statement per PR Notice 2007-4

Comments:

Based on a review of the material submitted, the following comments apply:

This application for notification to revise the product label, as referenced above, is acceptable. A copy has been placed in our records for future reference.

Should you have any questions or comments concerning this letter, please contact me at harris.monisha@epa.gov or call (703) 308-0410.

Sincerely,

Monisha Harris
Product Manager (32)
Regulatory Management Branch II
Antimicrobials Division (7510P)

CONCURRENCES

SYMBOL	7510P						
SURNAME	Harris						
DATE	9-12-11						

Please read instructions on reverse before completing form.

Form Approved OMB No. 2070-0060

Print Form



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 4959-16	2. EPA Product Manager Emily Mitchell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) ZZZ Disinfectant	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) West Agro, Inc. 11100 N. Congress Ave. Kansas City, MO 64153 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1, 5, 15, 30, 55, 275gal, and bulk		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Tammy Wright	Title Regulatory Specialist	Telephone No. (Include Area Code) 816.891-6971
2. Signature 		6. Detention Application Received (Stamped)
3. Title Regulatory Specialist		
4. Typed Name Tammy Wright		
5. Date 10Aug11		



Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504-P)
U.S. Environmental Protection Agency
1200 Pennsylvania, N.W.
Washington, DC 20460-0001

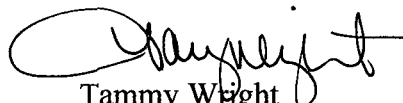
August 10, 2011

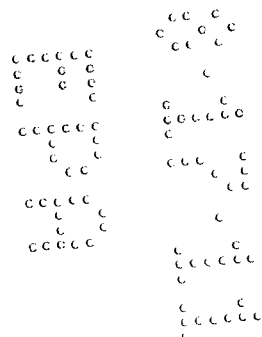
To Whom It May Concern:

Enclosed please find updated label copy for ZZZ Disinfectant, 4959-16. The label has been updated to reflect the required label changes covered in PR Notice 2007-4.

Thank you for your attention and assistance in this matter.

Regards,


Tammy Wright
Regulatory Specialist



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

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*, Hepatitis B; bactericidal against *Salmonella enterica*, *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 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 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* 1.75%

INERT INGREDIENTS: 98.25%

Total 100.00%

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

EPA Reg. No. 4959-16

EPA Est. No. 4959-IL-01

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.

NOTIFICATION

Date Reviewed: 9/12/2011
Reviewed By: [Signature]

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, 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.

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 enterica*,

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: 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 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. 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.

CONTACT TIME: 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.

DISPOSAL OF INFECTIOUS MATERIAL: Blood, body fluids, cleaning materials and clothing 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 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 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

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 Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying.

5 gallon or less containers - Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap.. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning if available. If not, puncture and dispose of in a sanitary landfill, or incineration, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Capacity greater than 5 gallon containers - Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning if available. If not, puncture and dispose of in a sanitary landfill, or incineration, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

Sold By: West Agro, Inc.
11100 N. Congress Ave.
Kansas City, MO 64153

NET CONTENTS:

LOT NO.:

Made in U.S.A.

415