

4959-16

7/17/2014

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

JUL 17 2014

Nannette Young  
West Agro Inc.  
11100 N. Congress Avenue  
Kansas City, MO 64153

Subject: ZZZ Disinfectant  
EPA Reg. No. 4959-16  
Submission Date: April 10, 2014  
Receipt Date: April 17, 2014

Dear Mr. Adams:

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

Label Amendment

- To remove the Tuberculosis claim

General Comments

Based on a review of the information submitted, the labeling amendment is acceptable. A stamped copy of the label is enclosed for your records. This labeling supersedes all previously accepted ones on file. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed labeling before you release this product for shipment bearing the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for up to 18 months from the date of this letter. After 18 months from the date of this letter you may only distribute or sell this product if it bears this new revised labeling of subsequently approved labeling.

Should you have any questions or comments concerning this letter, please contact Wanda Henson via email at [Henson.Wand@epa.gov](mailto:Henson.Wand@epa.gov) or call (703) 308-6345.

Sincerely,

A handwritten signature in black ink, appearing to read "Wanda Henson", is written over the typed name.

Demson Fuller  
Product Manager (32)  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

Enclosure: Stamped Label

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ZZZ™ DISINFECTANT IS A CONCENTRATED BROAD SPECTRUM DISINFECTANT FOR USE AS A ONE-STEP CLEANER-DISINFECTANT AND NO-RINSE SANITIZER IN:  
Hospitals and Clinics • Food Processing Plants • Dental Offices • Glove Hand Sanitizer  
• Schools and Institutions • Nursing Homes • Kitchens and Lunch Rooms • Restrooms  
VIRUCIDE, BACTERICIDE, FUNGICIDE  
Meets OSHA's Bloodborne Pathogens Act requirements

**! DANGER**

**! PELIGRO**

KEEP OUT OF REACH OF CHILDREN  
MANTENER FUERA DEL ALCANCE DE LOS NIÑOS

**PRECAUTIONARY STATEMENT:**  
HAZARD TO HUMANS AND DOMESTIC ANIMALS  
**DANGER:** Corrosive. Causes irreversible eye damage. Wear goggles or face shield when handling this product. Harmful if swallowed. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using tools. 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.

#### 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 dilute 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:** Non-refillable 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. Fill the container 3/4 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 rinse 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, 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.  
Capacity greater than 5 gallon containers: Triple-rinse as follows. Empty the remaining contents into application equipment or a mix tank. Fill the container 3/4 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 rinse 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, 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.

#### DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.  
This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced into the body, either into or in contact with the bloodstream or normally sterile areas 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.

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.  
Used as directed, ZZZ™ Disinfectant is effective in hard water (up to 400 ppm as CaCO<sub>3</sub>) 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 (bacteriophage against *Salmonella choleraesuis*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *E. Coli* fungicide 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<sub>3</sub>). ZZZ™ Disinfectant is effective against the HIV-1 virus on pre-cleaned environmental surfaces and objects previously soiled with blood or other body fluids.

(Directions continued on right panel)

0005-L0714

Manufactured by:  
West Agro, Inc.  
11100 N. Congress Ave.  
Kennesaw City, Missouri 64153

**WEST AGRO®**  
FOR INDUSTRIAL, INSTITUTIONAL AND AGRICULTURAL USE

## ZZZ™ Disinfectant

AUTHORIZED BY USDA FOR USE IN FEDERALLY INSPECTED  
MEAT, POULTRY AND EGG PROCESSING PLANTS

ACTIVE INGREDIENT: Iodine ..... 1.75%  
INERT INGREDIENTS ..... 98.25%  
Total ..... 100.00%  
\*from alpha-(p-nonylphenyl)-omega-hydroxyethylpolyoxyethylene-iodine complex

EPA Reg. No. 4959-16

EPA Est. No. 4959-IL-01 (C)  
4959-CA-01 (T)  
4959-TX-01 (D)

C, T, D - First letter of lot number indicates establishment

See left panel for additional precautions

| 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 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 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 by mouth 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 ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a Poison Control Center or doctor for treatment advice.                                           |
| Have product container or label with you when calling a Poison Control Center or doctor or going in for treatment. You may also contact 1-800-424-9300 for emergency treatment information. |                                                                                                                                                                                                                                                               |
| NOTED TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.                                                                                                   |                                                                                                                                                                                                                                                               |

#### DOT DESCRIPTION

**UN3264**

Corrosive liquid, acidic, inorganic, N.O.S.  
(contains Phosphoric Acid), 8, PG II

HAZARD RATING  
4-EXTREME  
3-HIGH  
2-MODERATE  
1-LOW  
0-INSIGNIFICANT



#### ONE-STEP CLEANING AND DISINFECTING:

This product may be used to clean and disinfect operating areas, patient rooms, floors, walls, countertops, restrooms, shower areas, refuse containers, bed frames, morgues, laboratories, cafeterias, commercial restrooms, 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. Use a solution of 5 ounces ZZZ™ Disinfectant per 5 gallons of warm water (80°F, 20°C or warmer), immerse objects in disinfecting solution, or apply solution with 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 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:** 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 body 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. Spray or 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-rinse 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.

**GLOVE SANITIZING DIRECTIONS:** To prevent cross contamination gloves must be sanitized prior to donning or re-donning those areas. Remove gross contamination from gloves before sanitizing. Then dip gloved hand in a use-solution of 1 ounce of ZZZ™ Disinfectant per 5 gallons of water so that there is enough sanitizing solution to cover the gloved area. Allow gloved hands to remain wet for at least 60 seconds. No portable water rinse is required. Change the solution in the bath at least daily or more often if the solution appears very cloudy or soiled.

| USE DILUTION TABLE      |                   |
|-------------------------|-------------------|
| ZZZ™ Disinfectant/Water | TITRATABLE IODINE |
| 1 oz to 5 gal.          | 25 ppm            |
| 3 oz to 5 gal.          | 75 ppm            |
| 5 oz to 5 gal.          | 125 ppm           |

**CHEM-TREC EMERGENCY # 1-800-424-9300**

NET CONTENTS:

LOT NO:

**ACCEPTED**

07/17/14

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