UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

4959-15

2/17/2006

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February 17, 2006

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

Subject:

XXX Disinfectant

EPA Registration No. 4959-15

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:

Proposed Notification

removal of HIV claims from label

General Comments

A stamped copy of the accepted labeling is enclosed. Submit 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								
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SURHAME .	.′	Henson						
DATE)		2-17-05			***************************************	• # 4 • • • • • • • • • • • • • • • • • • •	* * *****	
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FOR INDUSTRIAL INSTITUTIONAL AND AGRICULTURAL USE

XXX 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:

◆Veterinary Clinics ◆Poultry Drinking Water ◆Sanitizing Commercial Eggs ◆Egg Processing Plants ◆Dairy & Poultry Farms ◆ Meat & Poultry Plants ◆Food Processing Plants •Kennels, Pet Shops & Zoos •Hand Sanitizing in Food Plants •Animal Handling Facilities

TUBERCULOCIDE VIRUCIDE*, BACTERICIDE, FUNGICIDE, DEODORIZER

Used as directed XXX Disinfectant is effective in hard water (up to 400 ppm as CaCOs) and in 5% organic serum load against the following viruses, bacteria and pathogenic fungi: Polio 1", Vaccinia*, Herpes Simplex Type 1*, Influenza A2/Japan 305*, Hepatitis B and Canine Pervovirus*; bactericidal against Salmonella choleraesuis, Staphylococcus aureus, Pseudomonas aeruginosa, and E. Coli; is fungicidal against Trichophyton mentagrophytes (the athlete's foot fungus).

On pre-cleaned food contact surfaces XXX Disinfectant is effective against Salmonella choleraesuis, Listeria monocytogenes and Escherichia coli, 0157:H7, Hemorrhagic.

Used as directed XXX Disinfectant is tuberculocidal when used in hard water (up to 400 ppm as CaCO₃) on precleaned surfaces at 20 C for a contact time of 10 minutes. Prepare a solution of 3 punces XXX Disinfectant to 5 gallons water (provides 75 ppm titratable iodine).

ACTIVE INGREDIENT:

lodine*	1.75%
INERT INGREDIENTS:	98.25%
Total	100.00%

"From alpha-(p-nonytphenyt)-omega-hydroxypoly(oxyethytene)-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. Do not contaminate water by cleaning of equipment or disposal of wastes. Do not discharge efficient 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.

0006-0101

EPA Reg. No. 4959-15 EPA Est. No.

Under the Federal Insecticide, Fungicide Rodenticide, Act as amended, for the pesticide, registered under

EPA Reg. No. 🖊

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986	City,	MO	641	5.

	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 ON SKIN OR CLOTHING:	Take off conteminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes 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 include vomiting unless told to do so by the Poison Control Center or doctor. Do not give anything to an unconscious person.
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.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsion may be needed.

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 XXX Distrifectant 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:

PRIOR TO USE in Veterinary Clinics, Animal Handling Facilities, Farm Premises, Kennels, Pet Shops and Zoos: Remove all animals and feeds from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and all surfaces to be treated. Empty all troughs, racks and other feeding and watering appliances. Then proceed as directed below.

TO CLEAN AND DISINFECT: 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 XXX 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 brush. Where appropriate, use a mechanical sprayer to produce coarse spray. Allow a 10 minute contact time with disinfecting solution. For efficacy against Canine Parvevirus, allow a 120 minute contact time; surface must remain wet. All food contact surfaces must be ninsed with potable water before reuse. Floors, walls and all other non-food contact surfaces do not require rinsing before reuse.

NOTE: When using XXX Disinfectant against the following viruses, bacteria and pathogenic fungi. Polio 1*, Vaccinia*. Herpes Simplex Type 1*, and Influenza A2/Japan 305*, Salmonolla choleraesuis. Staphylococcus aureus, Pseudomonas aeruginosa. E. Coli, Trichophyton mentagrophyles, in a solution of colo water (as low as 41°F, 5°C), increase use to 6 oz. per 6 gallons water.

BEFORE REHOUSING ANIMALS: Ventilate buildings, vehicles and other closed spaces. Do not house animals or use equipment until treatment absorbs, sets or dries. Thoroughly rinse all treated feed racks mangers, troughs, automatic feeders, fountains and waterers with potable water before reuse.

SHOE BATH: Routine use of shoe bath sanitizers helps reduce the spread of disease causing organisms between poultry houses, farrowing houses, hog barns and other livestock buildings. Use 3 ounces of XXX Distrifectant per 1 gallon of water. Place sanitizing solution in shallow plastic or stainless steel pans inside all entrances to poultry and livestock buildings. Scrape shoes outside doorway and stand in shoe bath for 30 seconds before entering building. Replace shoe bath daily or more often if solution becomes soiled.

CLEANING MILKING EQUIPMENT AND BULK TANKS: Immediately after milking, flush milking equipment and utensils with lukewarm (100 F, 38 C) water to wash out all milk. Take apart milking machines and immerse air hoses, inflations, metal pans (except pulsator) and utensils in a solution containing 1 ounce of XXX Disinfectant per 5 gallons of water. Brush all parts thoroughly, rinse with water and allow to adequately drain. After emptying bulk tanks, flush tanks thoroughly with 100 F (38 C) water to wash out all milk. Brush tanks thoroughly with a solution containing 1 ounce XXX Disinfectant per 5 gallons of water. Allow wash solution to drain, rinse with water and allow rinse water to adequately drain.

SANITIZING MILKING MACHINES AND BULK TANKS: Before each milking, flush assembled milking machines and empty bulk tanks with a solution containing 1 ounce of XXX Disinfectant per 5 gallons of water. Allow a 1 minute contact time. Adequately drain before use,

REMOVAL OF MILKSTONE AND HARD WATER DEPOSITS: Yellow color may appear on equipment after the first use of XXX Disinfectant. This may indicate the presence of milkstone or hard water deposits. Remove these deposits by applying a solution containing equal parts of XXX Disinfectant and lukewarm water. Wait 2-3 minutes, brush and then tinse with potable water. Daily use of XXX Disinfectant will help prevent the formation of milkstone and hard water deposits.

SANITIZING POULTRY DRINKING WATER: Add 1 ounce of XXX Disinfectant per 10 gallons of drinking water. Regular use of this product in drinking water reduces the buildup of slime and mineral deposits in watering equipment. Do not use this product together with other water treatments such as medications.

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 XXX Disinfoctant per 5 gallons of water. Immerse equipment with sanitizing solution and allow 1 minute of contact time. Drain solution from equipment; do not rines XXX Disinfoctant 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:

- Pre-flush or pre-scrape equipment and utensits. If needed, pre-soak to remove gross food particles and soil.
- Wash equipment and utensils in tukewarm water that contains an adequate amount of a good detergent or cleaner. Keep this water clean by frequent changing.
- Rinse equipment and utensils free of wash water prior to sanitization.
- 4. Sanitize equipment and utensits by immersing them in a solution of 1 ounce XXX Disinfectant per 5 gallons of tukewarm water (provides 25 ppm titratable loadine). 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 loding test kit to check for proper concentrations.
- After required contact time of one minute or more, allow equipment and utensils to adequately drain. Do not rinse before use.

SANITIZING FOOD-GRADE EGG SHELLS: Coarse spray previously cleaned food-grade egg shells with a solution containing 1 ounce of XXX Disinfectant per 5 gallons of water. Solution temperature should be warmer than the eggs, but not to exceed 130 F (53 C). Wet eggs thoroughly for 1 minute and allow to drain. A final potable water rinse is not required. Eggs should be reasonably dry before casing or breaking. Do not reuse solution to sanitize eggs.

HAND SANITIZING: Thoroughly wash and rinse hands before sanitizing. Dip or rinse hands in a solution containing 1 ounce of XXX Disinfectant per 5 gallons of water. XXX 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.

DEODORIZING: XXX Disinfectant destroys many odors as it sanitizes and disinfects. For general deodorant applications (garbage pails, refuse containers, etc.), swab surface to be treated with a solution containing 1 ounce of XXX Disinfectant per gallon of water. Allow treated surface to adequately drain.

USE DILUTION TABLE

XXX DISINFECTANT/WATER=	TITRATABLE IODII	<u>NE</u>
1 oz to 10 gal.	12.5 ppm	
1 oz to 5 gal.	25 ppm	
3 oz to 5 gal.	75 ppm	
1 oz to 1 gal.	125 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.

NET CONTENTS:

ACCEPTED

FEB 1 7 2006

LOT NO:

Under the Federal Insecticide, Fungicide, and Rodenticide, Act as amended, for the pesticide, registered under FPA Req. No. 4

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