

December 15, 2004

Joy Seymour
West Agro Inc.
11100 N. Congress Avenue
Kansas City, MO 64153

Subject: XXX Disinfectant: Hepatitis B Virucidal Studies
EPA Registration No. 4959-15
Letter Date: December 30, 2003
Receipt Date: June 30, 2004

Dear Ms. Seymour:

This is in response to your letter dated November 17, 2003. The amendment submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is accepted with comments.

Comments

The language for "Special instructions for cleaning and decontaminating against HIV-1" must be removed from the label. This product does not make claims against HIV-1, therefore the language has been removed from the stamped label.

General Comments

A stamped copy of the accepted label is enclosed. Submit a copy of your printed label before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact Wanda Mitchell at (703) 308-6345.

Sincerely,

Emily H. Mitchell
Product Manager - Team 32
Regulatory Management Branch II
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL	7510C							
SURNAME	Mitchell							
DATE								

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 CaCO₃) 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 Parvovirus*; 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 pre-cleaned surfaces at 20 C for a contact time of 10 minutes. Prepare a solution of 3 ounces XXX Disinfectant to 5 gallons water (provides 75 ppm titratable iodine).

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. 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.

EPA Letter Dated:

0008-0101

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

DEC 15 2004

Sold By
 WEST AGRO, INC.

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

4959-15

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 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 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 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.	
<p style="text-align: center;">NOTE TO PHYSICIAN</p> 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 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:

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.

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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 Parvovirus, allow a 120 minute contact time; surface must remain wet. All food contact surfaces must be rinsed with potable water before reuse. Floors, walls and all other non-food contact surfaces may drain dry without rinsing.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1: Used in hard water (up to 400 ppm CaCO₃), XXX 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 into 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).

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 Disinfectant 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 parts (except pulsator) and utensils in a solution containing 1 ounce of XXX Disinfectant per 5 gallons of water. Brush all parts thoroughly. Drain completely, rinse with water and allow to air dry. 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 air dry.

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. Drain thoroughly and air dry 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 rinse 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.

NET CONTENTS:
LOT NO:

Made in U.S.A.
0006-0101

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 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. XXX 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 XXX 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.

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 drain and air dry.

USE DILUTION TABLE

<u>XXX DISINFECTANT/WATER=</u>	<u>TITRATABLE IODINE</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.

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