UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

December 15, 2004

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

Subject.

ZZZ Disinfectant: Hepatitis B Virucidal Studies

EPA Registration No. 4959-16 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								
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ZZZ Disinfectant is a concentrated broad spectrum iodophor for use as a one-step cleaner-disinfectant and no-rinse sanitizer.

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. Keep out of lakes, ponds or streams. 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 waters 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 first 5 minutes. Then continue finsing. Call a Poison Control Center or doctor for treatment advice.

IF ON SKIN: 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: 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 by mouth to an unconscious person.

IF INHALED: Move person to fresh eir. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call e 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 contact 1-800-424-9300 for emergency treatment information.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastic lavage. Measures against circulatory shock, respiratory depression and convulsions may be needed.

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 dump-

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 middance.

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

The color of a ZZZ DISINFECTANT solution is proportional to the titratable iodine concentration. Prepare a fresh solution deily, 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 CaCO₃) and in 5% organic serum load against the following viruses, bacteria and pathogenic fungi. Polio 1, Vaccinia, Herpes Simplex Type 1, and Influenza AZI,apan 305, Hepatitis 8: is bactericidal epainst Salmonella cholerasus. Staphylococcus aureus, Pseudomonas aeruginosa and E. Coli: is fungicidal egainst Trichophytron mentagrophytes (the athlete's foot fungus). ZSIDINFECT-TANT is effective against Listenia monocytogenes on pre-cleaned food contact surfaces. Used on Pre-cleaned environmental surfaces in hard water (up to 400 ppm CaCO₃, ZZZ DISINFECT-ANT is effective against Mycobacterium tuberculosis at 20°C for a contact time of 10 minutes.



FOR INDUSTRIAL USE ONLY

ZZZ DISINFECTANT

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

ACTIVE INGREDIENTS:

(oxyethylene)-iodine complex.

EPA Reg. No. 4959-16

EPA Est. No. 4959-IL-01 4959-OH-01 40871-CA-1

KEEP OUT OF REACH OF CHILDREN

DANGER. Corrosive. See left panel for additional precautionary statements.

For additional information, consult your West Agro, Inc. representative or the Material Safety Data Sheet (MSDS).

Manufactured By:

West Agro, Inc. 11100 North Congress Kansas Citv, Missouri 64153 Ruorder# 1-877-421 1905 HAZARD RATING 4-EXTREME

TOXICITY

3-HIGH 2-MODERATE 1-SLIGHT

1-SLIGHT 0-INSIGNIFICANT 0 REACTIVE

1 REACTIVE

SPECIAL

Chemtrec Emergency Number 1-800-424-9300 SPECIAL INSTRUCTIONS

Used in hard water (up to 40 HIV-1 Virus* on pre-cleaned or other body fluids. (This pre tant on any surface or instruents or in contact with the blaintact mucous membranes to wise enter normally sterile a decontaminate critical or ser fection).

DIRECTIONS FOR

It is a violation of federal law Not for Residential Use.

SANITIZING PREVIOUSLY

Sanitize previously cleaned a plastic, and porcelain, with a lons of water Immerse equip Drain solution from equipmen gallons of water contains 25 potable water in accordance

HAND SANITIZING IN FOO before sanitizing. Dip or rins TANT per 5 gallons of water rinse water at a rate of 1 our required.

ONE-STEP CLEANING AND

This product may be used to walls, counter tops, rest room oratories, cafeterias, comme surfaces. Before applying due removed from the room or ing the disinfecting solution, gallons of warm water (68°F, apply solution with a mop, si produce coarse spray. Allow contact surfaces must be rin contact surfaces may drain or

TO CLEAN AND DISINFEC of ZZZ DISINFECTANT direct including under the rim. Allo Rinse metal parts with water

ZZZ DISINFECTANT/ WATE 1 oz to 5 gal water 3 oz to 5 gal water

6 oz to 5 gal water

NET CONTENTS

LOT NO.:

0005-E1101 Made in USA