4959-34

10/25/2001

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 2 5 2001

Dollie Howser West Agro, Inc. 501 Santa Fe Kansas City, MO 64105

Subject: YYY Disinfectant EPA Registration Number 4959-34 Submission Dated June 19, 2001

Dear Ms. Howser:

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The labeling referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended to remove Livestock Drinking Water claim from the label, is acceptable subject to the comments listed below.

The claim for Livestock drinking water should be deleted below the "CONCENTRATED BROAD SPECTRUM IODOPHOR FOR USE AS A ONE-STEP CLEANER-DISINFECTANT AND NO RINSE SANITIZER IN:" heading.

A stamped copy of your labeling is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

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

Sincerely,

Robert S. Brennis Product Manager 32 Regulatory Management Branch II Antimicrobials Division (7510C)

CONCURRENCES					
SYMBOL 7510C					
SURNAME MITCHCI					
DATE 10-23-01					
Form 1320-1A (1/90)	Printed on Recycled Pape	OFFICIAL FILE COPY			

FOR INDUSTRIAL, INSTITUTIONAL AND AGRICULTURAL USE

YYY DISINFECTANT

CONCENTRATED BROAD SPECTRUM IODOPHOR FOR USE AS A ONE-STEP CLEANER-DISINFECTANT AND NO-RINSE SANITIZER IN:

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

 Dental Offices • Schools and Institutions • Nursing Homes • Kitchens and Lunch Rooms

TUBERCULOCIDE, VIRUCIDE*, BACTERICIDE, FUNGICIDE, DEODORIZER Meets OSHA's Bloodborne Pathogens Act requirement.

Used as directed, YYY DISINFECTANT is effective in hard water (up to 400 ppm $CaCO_{2}$) 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*, and Canine Parvovirus*; is bactericidal against Salmonella choleraesuis. Staphylococcus aureus, Pseudomonas aeruginosa, and E. Coli: fungicidal against Trichophyton mentagrophytes (the athlete's foot fungus).

YYY DISINFECTANT is effective against Listeria monocytogenes on precleaned food contact surfaces.

Used on pre-cleaned environmental surfaces in hard water (up to 400 ppm) CaCO₂), YYY DISINFECTANT is effective against Mycobacterium tuberculosis at 20°C for a contact time of 10 minutes.

Used in hard water (up to 400 ppm CaCO₃), YYY 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 the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection).

ACTIVE INGREDIENT:

Iodine**	0.35%	
INERT INGREDIENTS:	. <u>99.65%</u>	
Total		
* *From alpha-(p-nonvlohenvl)-omega-hydroxypoly(oxyethylene)-igdine complex		

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EPA Reg. No. 4959-34-EPA Est. No. ____-State-01 •Animal Handling Facilities •Hospitals and Clinics •Food Processing Plants Rooms •Restrooms PRECAUTIONARY STATEMENTS: Hazard to humans a 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

Do not get in eyes or on clothing. Avoid contact with skin. Wear goggles or face E 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 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 first 5 minutes. Then continue rinsing. 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 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 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.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

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, foud 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

Under the Federal heseficities and Rodenticide 200 Fungicide, and Roc amended, for the p registered under E LC. \sim ଞ

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Meat & Poultry Plants

•Food Processing Plants

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.

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 YYY 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.

AGRICULTURAL

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 3 ounce solution of **YYY DISINFECTANT** per 1 gallon of warm water (68°F, 20°C or warmer), immerse objects in disinfecting solution, or apply solution with 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 lood contact surfaces must be rinsed with potable water before reuse. Floors, walls and all other non-food contact surfaces may drain dry without rinsing.

<u>NOTE:</u> When mixing YYY DISINFECTANT with cold water (as low as 41°F, 5°C), increase use to 6 oz. per 1 gallon 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 15 ounces of YYY 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 YYY DISINFECTANT per 1 gallon 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 YYY DISINFECTANT per 1 gallon 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 YYY DISINFECTANT per 1 gallon 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 **YYY DISINFECTANT**. This may indicate the presence of milkstone or hard water deposits. Remove these deposits by applying **YYY DISINFECTANT** in its concentrated form. Wait 2-3 minutes, brush and then rinse with potable water. Daily use of **YYY DISINFECTANT** will help prevent the formation of milkstone and hard water deposits.

SANITIZING POULTRY DRINKING WATER: Add 1 ounce of YYY DISINFECTANT per 2 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 YYY DISINFECTANT per 1 gallon of water. Immerse equipment with sanitizing solution and allow 1 minute of contact time. Drain solution from equipment; do not rinse. YYY DISINFECTANT used at 1 ounce per 1 gallon 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 FOOD-GRADE EGG SHELLS: Coarse spray previously cleaned lood-grade egg shells with a solution containing 1 ounce of YYY DISINFECTANT per 1 gallon 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 YYY DISINFECTANT per 1 gallon of water. YYY DISINFECTANT may be injected directly into wash or rinse water at a rate of 1 ounce per 1 gallon of water. A final potable water rinse is not required.

DEODORIZING: YYY 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 5 ounces of **YYY DISINFECTANT** per gallon of water. Allow treated surface to drain and air dry.

USE DILUTION TABLE				
YYY DISINFECTANT/WATER =	TITRA TABLE I	<u>ODINE</u>		
1 oz to 2 gnl.	12.5	ppm		

	1 oz to	1 gal.	25	ppm
	3 oz to	1 gal.	75	ppm
ł	5 oz to	1 gal.	125	ppm
ť	5 oz to	1 gal.	150	ppm

INDUSTRIAL/INSTITUTIONAL

ONE-STEP CLEANING AND DISINFECTING:

This product may be used to clean and disinfect operating areas, patient rooms, floors, walls, counter tops, rest rooms, shower areas, refuse containers, bed frames, morgues, laboratories, cafeterias, commercial freezers, animal rooms, cages and other hard, non-porous 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 of YYY DISINFECTANT per 1 gallon of warm water (68 °F, 20 °C or warmer), immerse objects in disinfecting solution, or apply 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.

NOTE: When using cold water temperatures (as low as $41 \,^{\circ}$ F, $5 \,^{\circ}$ C) use a solution containing 6 ounces of **YYY DISINFECTANT** per 1 gallon of 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 or 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: While handling items soiled with blood or body fluids, use disposable latex gloves, gowns, masks and eye coverings (goggles or glasses).

CLEANING PROCEDURE: Before applying disinfecting solution thoroughly clean blood and other body fluids from hard surfaces, interior and exterior surfaces of objects to be decontaminated. Thoroughly wet hard surfaces with a solution containing 3 ounces of **YYY DISINFECTANT** per 1 gallon of water. Completely immerse objects in the disinfecting solution; avoid entrapment of air bubbles. Allow at least 10 minutes of contact time.

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids 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 5 ounces of YYY DISINFECTANT directly to water in 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 **YYY DISINFECTANT** per 1 gallon of water. Immerse equipment with sanitizing solution and allow 1 minute contact time. Drain solution from equipment; do not rinse. **YYY DISINFECTANT** used at 1 ounce per 1 gallon 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.

HAND SANITIZING IN FOOD PROCESSING PLANTS: Thoroughly wash and rinse hands before sanitizing. Dip or rinse hands in a solution containing 1 ounce of YYY DISINFECTANT per 1 gallon of water. YYY DISINFECTANT may be injected directly into wash or rinse water at a rate of 1 ounce per 1 gallon of water. A final potable water rinse is not required.

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 **YYY Disinfectant** per 1 gallon 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.

USE DILUTION TABLE

YYY DISINFECTANT/ WATER	TITRATABLE IODINE
1 oz to 1 gallon water	25 ppm
3 oz to 1 gallon water	75 ppm
6 oz to 1 gallon water	150 ppm

NET CONTENTS: LOT NO: Made in USA

0008-00