

4959-36

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 19, 2003

Ms. Dollie Howser
Regulatory Specialist
West Agro, Inc.
1100 N. Congress Avenue
Kansas City, MO 64153

Subject: **Rapidyne**
EPA Registration No. 4959-36
Your Application Dated April 23, 2003

Dear Ms. Howser:

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

Proposed Amendment:

- Response to PR Notice 2001-1

Label Comments:

- In the Precautionary statement add the letter (s) to swallowed in the second sentence (Harmful if "swallowed").
- Under the directions for use section in the first sentence replace the word "in" with "to" ("Rapidyne is...processing plants to insure sanitary...")
- In the Storage and Disposal subheading place the word "Pesticide" before Storage.

General Comment:

Add the statement "Do not contaminate water, food, or feed by storage or disposal" immediately below the Storage and Disposal heading.

A stamped copy of the accepted labeling is enclosed. Submit three (3) copies of your final printed labeling, before distributing or selling the product bearing the revised labeling.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

Renae A. Whitaker

of

Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510C)

Enclosure

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

WESTAGRO

FOR INDUSTRIAL USE ONLY

RAPIDYNE

GERMICIDE SANITIZER

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

ACTIVE INGREDIENTS:

Iodine*	3.50%
Phosphoric Acid	24.70%
INERT INGREDIENTS	71.80%
Total	100.00%

* From Polyethoxy polypropoxy polyethoxy ethanol-iodine complex

EPA Reg No. 4959-36

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

KEEP OUT OF REACH OF CHILDREN DANGER

CORROSIVE. See side 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 the 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 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: 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.

Manufactured By: West Agro, Inc.
11100 N. Congress Ave.
Kansas City, MO, 64153

RAPIDYNE is regulated by the U.S. Food and Drug Administration under the Food Additive regulation for use on food processing equipment and utensils up to 25 ppm of titratable iodine, without requiring a rinse with potable water.

PRECAUTIONARY STATEMENT: HAZARDS TO HUMANS AND DOMESTIC ANIMALS.



DANGER: Corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through skin or inhaled. Do not get in eyes, on skin or on clothing. Avoid breathing spray mist. Wear goggles or face shield. Wear protective clothing and rubber gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

PHYSICAL AND CHEMICAL HAZARDS: Mix only with water following label directions. Do not mix with chlorinated cleaners and sanitizers. Toxic chlorine gas will be formed. Contact with soft metals may generate hydrogen gas. Do not use or store near heat or open flame.

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 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.

STORAGE AND DISPOSAL

Storage: Keep container closed when not in use. Do not store below 0° F for extended periods.

Pesticide Disposal: Do not contaminate food, water. Or feed by storage or disposal. Pesticide wastes are acutely hazardous. Improper disposal of pesticide wastes or rinsate is a violation of Federal law. If these wastes cannot be disposed of 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 incineration or, if allowed by state and local authorities, by burning. 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.

RAPIDYNE is especially formulated for use by the bottling, beverage and food processing industries, as well as milk and ice cream processing plants in insure sanitary filling procedures, sanitizing filters, syrup lines, tanks, etc. RAPIDYNE, when used continuously as a sanitizing spray on walls, conveyors, equipment and floors, will sanitize surfaces and reduce or eliminate odors throughout the processing area. RAPIDYNE may be used as a sanitizer at 12 1/2 to 25 ppm titratable iodine throughout milk and ice cream processing areas and on filling equipment to reduce or eliminate E. Coli which are usually associated with condensation found on equipment, pipes, etc. In addition, continual use of RAPIDYNE as a sanitizer at 25 ppm will prevent the formation of milkstone on processing equipment. RAPIDYNE may be used at 25 ppm as a sanitizer in frozen and fresh-pack processing plants, and is effective in reducing cross-contamination. RAPIDYNE proportioned into pre-rinse of non-returnable bottles and final rinse of returnable bottles at 4 to 6 ppm will produce a final sanitized bottle.

RAPIDYNE is not adversely affected by common water hardness or low temperatures.

Follow your state and local Health Department requirements for sanitizing food processing equipment. For sanitizing equipment in meat, poultry, rabbit and egg processing plants, clean surfaces with detergent wash and rinse with potable water. Final rinse with a solution of 1 ounce of RAPIDYNE and 13 gallons of water, allow a one minute contact time.

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

NOTE: RAPIDYNE IS A CONCENTRATE AND MUST BE DILUTED BEFORE USE.

USE DILUTION TABLE

RAPIDYNE	WATER	TITRATABLE IODINE
2 oz.	13 gallons	50 ppm
1 oz.	13 gallons	25 ppm
1 oz.	30 gallons	10 ppm

NOTE: RAPIDYNE is recommended for use in stainless steel equipment only.

FOR USE IN PLANTS

SOFT DRINK IN-PLACE SANITIZING

For one-step in-place sanitizing of bottling or pre-mix dispensing equipment, thoroughly rinse equipment with cold or lukewarm water. Fill equipment with a solution of 1 oz. RAPIDYNE to 13 gallons of water (25 ppm titratable iodine). Allow the solution to remain in contact with the equipment until operations resume, at least one minute. Drain sanitizing solution from the system. To insure the thorough removal of flavors, it is suggested that during change-over between products, the system should be flushed with a sanitizing solution of RAPIDYNE. Rinse thoroughly with water before the use of sanitizing solution (1 ounce of RAPIDYNE to 13 gallons of water).

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For sanitizing and disinfecting exterior portions of the equipment, thoroughly wet and scrub surface with a solution of 2 oz. of RAPIDYNE to 13 gallons of water. Rinse before use.

SANITARY FILLING

RAPIDYNE is recommended for use in sanitizing bottles and cans in the final rinse application. RAPIDYNE is proportioned into the final rinse water line of the container washer or rinser in a concentration of 8 to 12 ppm. The exact concentration required will be determined by local conditions. Allow one minute contact time. A RAPIDYNE solution containing 20 to 25 ppm should be used in a external spraying application for the filler and closing machine. RAPIDYNE is also recommended for use in the internal filler sanitation program.

STORAGE TANK SANITIZING

RAPIDYNE is recommended for sanitizing beer fermentation and holding tanks. A solution of 20 to 25 ppm should be applied by spraying or used in combination with automated cleaning systems. A final fresh-water rinse is not recommended.

RAPIDYNE cleans and brightens cans.

RAPIDYNE helps reduce the growth of microorganisms in retort cooling water.

RAPIDYNE should be added to the retort cooling water in sufficient quantity to maintain 0.1 to 0.5 ppm titratable iodine at the discharge side. To reach this level of iodine, an initial concentration of 5 ppm titratable iodine is recommended (1 oz. RAPIDYNE to 55 gallons of water). The amount of RAPIDYNE required will depend on the organic load and the alkalinity of the water. A suitable iodine test kit, capable of measuring iodine in the range of 0.1 to 0.5 ppm, should be used to check iodine levels.

FOR USE IN DAIRIES

MILKING CLAW SYSTEM

For use through claws between milking each cow. Helps reduce microorganisms on liners which may cause mastitis.

1. Pre-rinse thoroughly with potable water or a thoroughly mixed solution containing 1 oz. of RAPIDYNE per 13 gallons of water. This solution provides 25 ppm titratable iodine.
2. Flush system with a thoroughly mixed solution containing 1 oz. of RAPIDYNE per 13 gallons of water. Allow at least one minute contact time.
3. Thoroughly drain system.

WASH DOWN HOSES

For general cleaning in the milking parlor use a thoroughly mixed solution containing 1 oz. of RAPIDYNE per 13 gallons of water. Thoroughly hose down surfaces.

IMPORTANT: Follow state and local Health Department requirements for sanitizing milking equipment. Do not mix RAPIDYNE with hot water. Use cool or tepid water only.

FOR USE AS AN UDDERWASH

To clean cow's teats before milking, use a well mixed solution containing 1 oz. of RAPIDYNE per 13 gallons of water. Wash teats and flanks thoroughly, then dry with a clean single service paper towel.

U.S. PATENT NO. 3, 650,965

ACCEPTED
with COMMENTS
EPA Letter Dated:

JUN 19 2003

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

4959-36

NET CONTENTS:

LOT NO.:

EXPIRATION DATE: