

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Stacey Coats
West Agro
501 Santa Fe
Kansas City, MO 64105-1113

JUL 27 2000

Dear Ms. Coats:

Subject: Confirmatory data for additional Organism claims
Rapidyne® Germicide Sanitizer
EPA Registration No. 4959-36
Your resubmission of January 18, 2000

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, section 3 (c) (7) (A), as amended, is acceptable provided that you make the labeling changes indicated below prior to release for shipment of product bearing the amended labeling:

Revise the precautionary statements to read:

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.

FIRST AID STATEMENT

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 or doctor for treatment advice.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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. Do not induce vomiting. Drink promptly a large quantity of milk, egg white, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

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.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Submit two copies of your final printed labeling before you release the product for shipment. A stamped copy is enclosed for you records.

Sincerely yours,

for Adam Heyward

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

Enclosure

WESTAGRO®

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUL 27 2000

FOR INDUSTRIAL USE ONLY

RAPIDYNE® Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
GERMICIDE SANITIZER registered under EPA Reg. No. 4959-36

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
40871-CA-1

**KEEP OUT OF REACH OF CHILDREN
DANGER**

CORROSIVE. See side panel for additional precautions.

STATEMENT OF PRACTICAL TREATMENT

If Swallowed: Drink promptly a large quantity of water. Do not induce vomiting. Avoid alcohol. Get medical attention.

If In Eyes: Flush with plenty of water for 15 minutes. Get medical attention.

If On Skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

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

Manufactured By:

West Agro, Inc.
11100 North Congress
Kansas City, Missouri 64153
Reorder# 1-800-421-1905

HAZARD RATING
4-EXTREME
3-HIGH
2-MODERATE
1-SLIGHT
0-INSIGNIFICANT



CHEM-TREC EMERGENCY #
1-800-424-9300

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 STATEMENTS

Hazardous to humans and domestic animals



Corrosive. Causes eye damage and skin irritation. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Avoid contamination of food. Wear goggles and rubber gloves when handling. Avoid breathing fumes or vapors. Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to fish. 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.

STORAGE AND DISPOSAL:

STORAGE: Keep container closed when not in use.

DISPOSAL: Do not store below 0°F for extended periods. Do not contaminate water, food or feed by storage or 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.

Triple rinse. Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incinerator, 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 to 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 milk stone on processing equipment. RAPIDYNE may be used at 25 ppm as a sanitizer in frozen and fresh-pack processing plants, and is most 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.

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

0198

Made in USA

DIRECTIONS FOR USE CONTINUED

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 choleraesuis*, *Listeria monocytogenes* and *Escherichia coli*, O157:H7, Hemorrhagic.

RAPIDYNE IS A CONCENTRATE AND MUST BE DILUTED BEFORE USE.

USE DILUTION TABLE

RAPIDYNE	WATER	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 PLANTS 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 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 oz. of RAPIDYNE to 13 gallons of water). 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 or cans in the final rinse application. RAPIDYNE is proportioned into the final rinse water line of the container washer or rinser in 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 an 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. of 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 titratable 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.

Step #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.

Step #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.

Step #3 Thoroughly drain system.

WASH DOWN HOSES: For general cleaning in the milk parlor, use a thoroughly mixed solution containing 1 oz. of RAPIDYNE per 13 gallons of water. Thoroughly rinse down all surfaces.

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

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.

LOT NO:

NET CONTENTS:

EXPIRATION DATE: