

66171-7

8-22-2006

1/3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 22 2006

Mr. Gary Gunner
Preserve International
P.O. Box 17003
Reno, NV 89511

Subject: Synergize
EPA Registration No.: 66171-7
Amendment Date: February 16, 2006
EPA Receipt Date: February 27, 2006

Dear Mr. Gunner,

The following amendment submitted in connection with registration under FIFRA section 3(c)(7)(A) is acceptable with conditions listed below.

- Add Additional Organisms, Avian Influenza A (H3N2) virus (Avian Reassortant) and Escherichia coli (F-18)

Conditions

Revise the label as follows:

1) The species name of *Salmonella choleraesuis* (ATCC 10708) has been changed by ATCC to *Salmonella enterica*. Your label will need to reflect this organism name change. Also, you must list the ATCC virucidal designation for Avian Influenza by stating Avian Influenza A (H3N2) virus (Avian Reassortant).

2) Fiberglass is a porous surface. You must qualify fiberglass as a hard nonporous surface by listing specific surfaces made of sealed fiberglass such as sinks and tubs."

3) After #7 under the "Directions for use in Poultry House," add the heading, "Directions for Hatchery Room Fogging." Revise the directions to reflect the following:

Remove all animals, feed, food products and packaging from premises. Remove all litter and manure from floors, walls, and surfaces of room to be treated. Thoroughly clean all surfaces with soap or detergent and rinse with water. Close room off so fog is confined to room to be treated. Mix 0.25 to 1 oz per gallon of water then fog using one quart per 1000 cubic feet of room area. When fogging is complete ventilate building and other closed spaces. All areas of personnel, poultry, and feeds must be vacated for a minimum of 2 hours after fogging.

Thoroughly clean all food contact surfaces including feeding and watering appliances with soap or detergent and rinsed with potable water

RECORD DATES							
SYMBOL							
SURNAME							
DATE							

Acceptable Data

Data Requirement	Means of Support	Status
Virucidal Efficacy of Disinfectants - Avian Influenza A (H3N2) virus (Avian Reassortant)	Submitted study, MRID 467703-01	Acceptable, 1:256 dilution in 5% serum for 10 minutes in 1000 ppm hard water
AOAC Use Dilution Method - E. coli (F-18)	Submitted study, MRID 467703-02	Acceptable, 1:256 dilution in 5% serum for 10 minutes in 1000 ppm hard water

General Comments

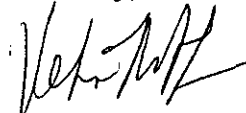
A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/re-registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions or comments concerning this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,



Velma Noble
 Product Manager (31)
 Regulatory Management Branch I
 Antimicrobials Division (7510C)

Enclosure: Stamped Label
 Efficacy Data Evaluation

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleaner. SYNERGIZE provides a broad spectrum kill of gram negative and gram positive microorganisms. SYNERGIZE provides effective disinfecting and cleaning in one operation. SYNERGIZE is effective in warm, soft or hard water (as much as 1000 ppm CaCO₃) and performs especially well in areas containing 5% serum.

SYNERGIZE is for use on glazed ceramic and tile surfaces, stainless steel, aluminum, chrome, galvanized metal, tin, brass, zinc, glass, hard non-porous treated wood, polyethylene, polypropylene, PVC (polyvinyl chloride), vinyl, fiberglass, viton, ethylene propylene, nitrile, acrylic and polyurethane.

DIRECTIONS FOR USE:

It is in violation of Federal Law to use this product in a manner inconsistent with its labeling. Registered for disinfecting and cleaning hard non-porous surfaces. Not for use on feed, food or litter.

SYNERGIZE cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, refrigerator exteriors, telephone booths and garbage cans in non-animal areas associated with the sites noted above. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) to pre-cleaned surfaces. Apply with cloth, sponge, mop or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes. All surfaces must be rinsed with clean water and allowed to dry before reuse.

BOOT/SHOE WASH: To prevent tracking harmful organisms into animal areas, shoe baths containing one inch of freshly made disinfecting solution should be placed at all entrances to building. Scrape waterproof shoes or boots and place in a 1/2 ounce SYNERGIZE per gallon water solution. Allow the solution to come in contact with the boot/shoe for 10 minutes. Change the disinfecting solution when solution becomes visibly dirty.

VEHICLES: To disinfect the non-porous, hard surfaces of vehicles use a solution of 1/2 ounce SYNERGIZE per gallon of water. Apply using a high pressure or course spray system. Leave all treated surfaces exposed to solution for 10 minutes, or more and allow to air dry. All treated surfaces that will contact feed or drinking water must be thoroughly scrubbed with soap or detergent then rinsed with potable water before reuse.

DIRECTIONS FOR USE IN SWINE PRODUCING FACILITIES:

- 1) Remove all animals and feed from the premises, vehicles and enclosures.
- 2) Empty all troughs, racks, and other feeding and watering appliances.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from walls to ceilings of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 6) Allow all treated areas to remain in contact with this solution for at least 10 minutes.

7) Immerse equipment used in handling and restraining animals, forks, shovels, and scrapers used for removing manure in SYNERGIZE at a dilution of 1:256. Allow to remain in contact for at least 10 minutes.

8) Ventilate buildings, and other closed spaces. Do not house swine or other livestock until treatment has been absorbed, set, or dried.

9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

DIRECTIONS FOR USE IN FARM PREMISES, EQUINE FACILITIES, VEAL BARN, RATITES FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milk houses.
- 2) Remove all animals and feed from the premises, vehicles, and enclosures.
- 3) Remove all gross soil, bedding, manure, caked on dirt, spider webs, etc. from floors, surfaces, and from walls to ceiling of barns, pens, stalls, chutes, and other facilities occupied or traversed by hogs or other animals.
- 4) Empty all troughs, racks, and other feeding and watering appliances.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods. Allow to remain in contact with this solution for at least 10 minutes.

Manufactured By:



Zephyr Cove, NV 89448 (209) 664-1607 • www.preserveinternational.com

SYNERGIZE CLEANER-DISINFECTANT

Synergize cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, Hatcheries and Swine Producing Facilities as well as the following equipment in these facilities: Waterers, Feeders, Hauling Equipment, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premise, Equine Facilities, Veal Barns, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

Staphylococcus aureus A.T.C.C. 6538

Pseudomonas aeruginosa A.T.C.C. 15442

Salmonella choleraesuis A.T.C.C. 10708

Aspergillus fumigatus A.T.C.C. 36607

Porcine Respiratory & Reproductive Syndrome Virus (PRRS)

Avian Influenza

Escherichia Coli F18

ACTIVE INGREDIENTS

Alkyl (C₁₂ 67%, C₁₁ 25%, C₁₀ 7%, C₉ 1%) dimethyl benzyl ammonium chloride26.00%

Glutaraldehyde7.00%

INERT INGREDIENTS67.00%

TOTAL100.00%

KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed, by storage and disposal.

PESTICIDE STORAGE:

Store away from heat. Do not transfer to another container. Do not reuse empty container

CONTAINER DISPOSAL:

Plastic: 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.

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 of the Hazardous Waste Manifest, or the nearest EPA Regional Office for guidance.

EPA Registration No.: 66171-7

EPA Establishment No.: 66171-N-90

66171-CA-101

Patent Number: 5,891,922

NEPA HAZARD CLASSIFICATION			
HEALTH	FIRE	REACTIVITY	SPECIFIC HAZARD
3	1	1	None

- 7) Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels and scrapers used for removing manure in a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256). Allow to remain in contact for 10 minutes.
- 8) Ventilate buildings, cars, boats, coops and other closed spaces. Do not house poultry or livestock or employ equipment until treatment has been absorbed, set or dried.
- 9) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

DIRECTIONS FOR USE IN POULTRY HOUSE:

- 1) Remove all poultry and feeds from premises, trucks, coops, and crates.
- 2) Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
- 3) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 5) Saturate surfaces with 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes.
- 6) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set, or dried.
- 7) Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains, waterers and equipment which may come in contact with food with soap or detergent, and rinse with potable water before reuse.

Prior to fogging setters or hatchers, food products and packaging must be removed from the room or carefully protected. After cleaning, fog desired areas using one quart per 1000 cubic feet of room area with a product solution containing 0.25 to 1 ounce per gallon water. Vacate all areas of personnel and poultry and feeds for a minimum of 2 hours after fogging. All food contact surfaces, including feed troughs, automatic feeders, and fountains must be disinfected followed by treatment with soap and water or detergent and rinsed with potable water before reuse.

*NOTE: The fog generated is very irritating to eyes, skin, and mucous membranes. Under no circumstances should a room or building be entered by anyone within two hours of the actual fogging. If the building or room must be entered, then the individuals entering the building must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeves and long pants.

FOGGING IS TO BE USED AS AN ADJUNCT TO ACCEPTABLE MANUAL CLEANING AND DISINFECTION OF ROOM AND MACHINE SURFACES.

PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

DANGER

KEEP OUT OF REACH OF CHILDREN. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Wear goggles or face shield. Wear a dust/mist/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) or a NIOSH approved respirator with any N, P, R, or HE prefilter. Wear protective clothing and rubber gloves. Prolonged or frequent repeated skin contact may cause allergic reaction in some individuals. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT

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 eye; call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: 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 INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible; call a poison control center or doctor for further 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.

HOT LINE NUMBER: 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) 255-3924 for emergency medical treatment information. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Telecommunications Network at 1 (800) 858-7378.

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

ENVIRONMENTAL HAZARDS: This product is toxic to fish. Do not apply directly to water. 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.

Net Contents: _____ U.S. Gallons Batch No.: _____