

66171-7

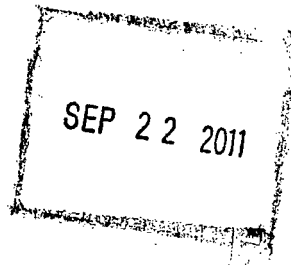
9/22/2011

1/4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Gary E. Gaumer
Preserve International
P.O. Box 17003
Reno, NV 89511

Subject: Synergize
EPA Registration No.: 66171-7
Amendment Date: May 16, 2011
EPA Receipt Date: June 1, 2011



Dear Mr. Gaumer,

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), section 3(C)(7)(A) is acceptable subject to the comments listed below.

- Addition of Air Washers and Industrial Scrubbing Systems
- Addition of Canine parvovirus

Conditions

1. Revise the first section on page 2 to begin as follows: "All surfaces must be cleaned and disinfected in accordance with label directions prior to fogging..."
2. Make the following corrections to section C) Poultry Houses and Livestock Buildings: add quotation marks after the phrase: "...calf pens and vehicles". Add mandatory language as per PR 2000-5 as follows: "...The Fogger itself is placed just inside...the nozzle of the fogger is inserted..."
3. Add mandatory language to the Air Washers and Industrial Scrubbing section as follows: "This product is used in industrial air washers..." "...Addition is made intermittently..." "...Badly fouled systems are shock treated..." "Synergize is used in industrial process water..."
4. In the Air Washers and Industrial Scrubbing section, Continuous Feed Method, Subsequent Dose revise to read as follows replacing the first statement with: "Maintain this treatment level by starting a continuous feed of 1 to 4 ounces per 100 gallons of water lost to blowdown. Badly fouled systems"

CONCURRENCES

| | | | | | | | |
|---------|----------------|--|--|--|--|--|--|
| SYMBOL | 7510P | | | | | | |
| SURNAME | J. [Signature] | | | | | | |
| DATE | 9/22/11 | | | | | | |

5. Delete the following incorrect statement from the Veterinary Practice section. This statement is not appropriate as the beginning of this section indicates that the product is not for treatment of equipment used for animal food or water. Delete: "Thoroughly scrub treated feed racks, automatic feeders, waterers and other equipment which dispenses food or water with soap or detergent and rinse with potable water before reuse."

General Comments

A stamped copy of the accepted labeling is enclosed. Submit one (1) copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3 (c) (5) and section 4 (a) 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 concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



for

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

7510P:T.Lantz:9/22/11:66171-7k

| CONCURRENCES | | | | | | | |
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| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
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DESCRIPTION

SYNERGIZE is a multi-purpose disinfectant-cleanser. 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, sealed 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 food, food or filler.

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: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premises, Veal Barns, Rattle Facilities (Ostrich, Emu and Rhea Facilities), Equine Facilities, Calf Pens and associated Farm Facilities, Veterinary Practice, Animal Care, and Animal Laboratory.

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/SOUE WASH: To prevent cross contamination into animal areas, shoe baths containing one inch of freshly made disinfecting solution must 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 coarse 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. Thoroughly saturate all surfaces with a solution of 1/2 oz. SYNERGIZE per gallon of water (1:256), using conventional spraying methods.
- 5) Do not use in milking parlors, milking parlors, or milking parlors.
- 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, RATTLE FACILITIES, CALF PENS AND VEHICLES:

- 1) Do not use in milking stalls, milking parlors, or milking parlors.
- 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.

ACCEPTED
with COMMENTS
in EPA Letter Dated: _____

66171-7
66171-TN-001, 66171-CA-001
5,891,922

EPA Reg. No. _____
EPA Est. _____
Patent Number: _____

Batch No.: _____ Net Contents: _____

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 66171-7

www.preserveinternational.com

SYNERGIZE CLEANER-DISINFECTANT

STAPHYLOCIDAL • PSEUDOMONACIDAL
• SALMONELLACIDAL • VIRUCIDAL*
• PARVOCIDAL • FUNGICIDAL
ASPERGILLOCIDAL

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: Waterers, Feeders, Hauling Equipment, Dressing Plants, Loading Equipment, Farrowing Barns, Nurseries, Blocks, Creep Areas, and Chutes. This product is also for use in Farm Premises, Veal Barns, Rattle Facilities (Ostrich, Emu and Rhea Facilities), Equine Facilities, Calf Pens and associated Farm Facilities, Veterinary Practice, Animal Care, and Animal Laboratory.

Active Ingredients:

| | |
|---|---------|
| Alkyl (C12 67%, C14 25%, C16 7%, C18 1%) dimethyl benzyl ammonium chloride..... | 26.00% |
| Glutaraldehyde..... | 7.00% |
| Inert Ingredients..... | 67.00% |
| TOTAL..... | 100.00% |

KEEP OUT OF REACH OF CHILDREN DANGER

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

See First Aid statement and additional precautions on side panel

- 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.

Manufactured by:
PRESERVE
INTERNATIONAL

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.

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 instruction, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or offer for reconditioning if appropriate, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

(For greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container 1/4 full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Dispose of rinsate as noted in the pesticide disposal section. Repeat this procedure two more times. (For 5 gallons or less) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Dispose of rinsate as noted in the pesticide disposal section. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

General: Consult Federal, State or local disposal authorities for approved alternative procedures.

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/filtration 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.

ENVIRONMENTAL HAZARDS: This product is toxic to fish aquatic invertebrates, oysters, and shrimp. 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.

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes; call 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.

