

66171-7

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

FEB 16 2012

SUBJECT: Synergize
EPA Registration Number: 66171-7
Application Date: August 31, 2011
Receipt Date: September 7, 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 with the condition below.

- On page 2 of the proposed label in the section B) INCUBATORS AND HATCHERS, the statement "disperse the sanitizing solution as a fog" must be revised as the fogging use is only an adjunct treatment (Agency letters of 12/30/2010 and 7/23/2010). Revise this statement to read "...disperse the solution as a fog..." by deleting the word "sanitizing".

Efficacy Data

The following study has been reviewed in support of this product. The review of this data is attached.

Data Requirement	Means of Support	Status
Salmonella enteric subsp. enterica serovar enteritidis (ATCC 13076)	Submitted study, MRID 485944-01	Acceptable, 1/2 ounce product per 1 gallon of water, 5% soil, contact time of 10 minutes

General Comments

A stamped copy of the accepted labeling with conditions is enclosed. Submit 1 copy of your final printed label before distributing or selling the product bearing the revised labeling.

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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 Emilia Oiguenblik at (703) 347-0199 or Velma Noble at (703) 308-6233.

Sincerely,



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

Attachments: Stamped label and Efficacy review DP Barcode: D394286

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 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 Premises, Equine Facilities, Veal Barns, Rattite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, 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

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 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 Premises, Equine Facilities, Veal Barns, Rattite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles.

USE DIRECTIONS:
 1) 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 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.
- 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 rappers 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 BARNs, RATTITE 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:

Reno, NV 89511 • (800) 995-1607 • www.preserveinternational.com
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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 dustmisting respirator (MSHA/NIOSH approval number PRX-21C1) or a NIOSH approved respirator with any N, P, R, or HE filter. 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; 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) 295-3924 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.

66171-7

ACCEPTED
 with COMMENTS
 in EPA Letter Dated: FEB 16 2012
 EPA Reg. No. 66171-TN-001, 66171-CA-001
 EPA Est. 5,894,922
 Patent Number: 66171-7

Batch No.: Net Contents: _____
 FEB 16 2012
 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 66171-7

SYNERGIZE

HATCHERY ROOMS, INCUBATORS, AND HATCHERS, POULTRY HOUSES AND LIVESTOCK BUILDINGS BY FOGGING:

All surfaces must be cleaned and disinfected prior to fogging. Fogging is an adjunct or supplement to normal cleaning and disinfection procedures and practices. Fogging is not used as a sanitizing treatment. Close room off so fog is confined to room to be treated. Wear a dust mist respirator when mixing the use solution and pouring it into the fogging apparatus.

A) HATCHERY ROOMS:

Remove all animals and feed from premises, vehicles and enclosures. Close room off so fog is confined to room to be treated. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. Do not allow people to breathe or contact the fog or to enter the room until the fog has completely settled or exhausted. Normally this is 1-4 hours in this environment.

B) INCUBATORS AND HATCHERS:

Only for treatment of setters and hatchers after poultry / chicks / eggs have been removed. Not for treatment of hatchers which contain chicks / eggs. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water. Fog three (3) ounces per 100 cubic feet of this fogging solution into setters and hatchers immediately after transfer. Repeat daily. Discontinue Hatcher treatments approximately 24 hours before pulling the hatch. Do not allow people to contact or breathe this fog and do not enter machines until the fog has settled (30-60 minutes after fogging is completed). To do this, install permanent fogging nozzles in setters and hatchers and use an air compressor to disperse the solution as a fog. It is also satisfactory to fog setters and hatchers with a 1:1000 solution of SYNERGIZE. If this is done, fog for 30-90 seconds once per hour or once every two hours.

C) POULTRY HOUSES AND LIVESTOCK BUILDINGS:

After the house has been depopulated and cleaned as in "Directions for use in farm premises, equine facilities, veal barns, rattle facilities, calf pens and vehicles, double check to be sure all people, poultry, livestock and pets have vacated the building. Close all windows, doors, curtains, etc. making the house as closed as possible. Prepare a stock solution of one (1) part SYNERGIZE to four (4) parts water (25 fluid ounces SYNERGIZE to 100 fluid ounces water). Insert the nozzle of the fogging device through a suitable opening in the room. With the setting on maximum output, fog 125 fluid ounces for each 1000 cubic yards. The Fogger itself may be placed just inside the door of the building to be treated, or the nozzle of the fogger may be inserted through a suitable opening in the door or building. The opening must be large enough to accommodate the nozzle. After fogging, the building must be kept closed for twenty-four (24) hours. After twenty-four (24) hours, the fog must have settled and the house can now be opened and aired. The house must be opened for a minimum of twenty-four (24) hours before it is repopulated with poultry or livestock.

NOTE: The generated fog is very irritating to eyes, skin, and mucous membranes. Under no circumstances must a room or building be entered by anyone until the fog has completely settled. A reentry time of two (2) hours is required. If the building or room must be entered, then the individuals entering the building or room must wear a self contained respirator approved by NIOSH/MSHA, goggles, long sleeve shirt and pants. If feeders and waterers were not removed from the premises during treatment, or were not adequately covered to prevent contact with the treatment, they must be washed with detergent and water before use for poultry or livestock.

AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS / RECIRCULATING COOLING AND PROCESS WATER SYSTEMS:

This product may only be used in industrial air washers and air washer systems which have mist-eliminating components. SYNERGIZE must be added at the application rates described below to a water treatment system at a convenient point of uniform mixing such as a basin area. Addition may be made intermittently (Slug Dose) or continuously. Badly fouled systems can be shock treated with SYNERGIZE. Under these conditions, blowdown must be discontinued for up to 24 hours.

SYNERGIZE can be used in industrial process water systems that contain ultra filtration units and non-medical reverse osmosis membranes (Where approved for compatibility by the membrane manufacturer) and associated distribution systems.

Intermittent (Slug Dose) Method:

Initial Dose: When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

Subsequent Dose: When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

Continuous Feed Method:

Initial Dose: When the system is noticeably fouled, apply 2.0 to 4.0 ounces of SYNERGIZE per 100 gallons of water in the system. Repeat until control is achieved.

Subsequent Dose: When microbial control is evident, add 1.0 to 3.0 fluid ounces of SYNERGIZE per 100 gallons of water in the system weekly, or as needed to maintain control. Badly fouled systems must be cleaned before treatment is begun.

VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORY/ANIMAL LIFE SCIENCE LABORATORY/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOO/PET SHOP/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREEDING FACILITIES/BREEDING AND GROOMING ESTABLISHMENT/TACK SHOPS/INFECTIOUS DISEASES: For cleaning and disinfecting the following hard, non-porous surfaces: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, stalls and catenies. Remove all animals (and) feeds from areas to be treated, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply a solution of 1/2 ounce SYNERGIZE per gallon water (dilute 1:256) for a period of 10 minutes. 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 litter and manure. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried. Thoroughly scrub all 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. At 1/2 ounce per gallon of water, in the presence of 1000 ppm of hardness and 5% organic load for a 10-minute contact time, this product was found to be effective against Canine Parvovirus.

Staphylococcus aureus A.T.C.C. 6538
Salmonella Choleraesuis
Salmonella Enteritidis

Pseudomonas aeruginosa A.T.C.C. 15442

Salmonella enterica A.T.C.C. 10708

Aspergillus fumigatus A.T.C.C. 36607

Porcine Respiratory & Reproductive Syndrome Virus (PRRS)*

Avian Influenza (H3N2)*

Escherichia Coli F18

Porcine circovirus Type 2*

Canine parvovirus A.T.C.C. VR-2016*

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DOT SHIPPING NAME

UN3264, Corrosive Liquid, Acidic, Inorganic,
n.o.s. (Phosphoric Acid), 8, PG III

12/7/11

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