



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 27, 2021

Grace Rapai
Regulatory Specialist II
Preserve International
944 Nandino Blvd
Lexington, KY 40511

Subject: PRIA Label Amendment – Revise Toxicity Category Based on New Data
Product Name: Synergize RTU
EPA Admin Number: 66171-107
Application Date: August 11, 2021
Case Number: 00316157

Dear Ms. Rapai:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Mohammad Alavi by phone at (202) 566-0922, or via email at Alavi.mohammad@epa.gov.



Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

{Note to reviewer: Items within (parentheses) are optional, and may or may not remain in parentheses on the final label. Text within [brackets] is interchangeable, e.g., [This product] could also be product brand name and formatting may be changed (e.g., ALL CAPS, Head-Caps, bold). Standard abbreviations are acceptable for common measurements, such as ounces (oz.) or liters (L). Text within {braces} is informational and will not appear on the final label.}

SYNERGIZE™ RTU
[CLEANER-]DISINFECTANT
BACTERICIDAL* • VIRUCIDAL* • FUNGICIDAL
***See Directions for Use for list of approved organisms.**

[This product] [cleaner-disinfectant is specifically formulated for industrial use in the following Animal and Poultry Housing facilities: Turkey, Breeder, Grow Out, Fryer, Layer, 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, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practices, Animal Care Facilities, and Animal Laboratories.]

Active Ingredients:

Alkyl (C₁₂ 67%, C₁₄ 25%, C₁₆ 7%, C₁₈ 1%) dimethyl benzyl ammonium chloride.....0.102%
Glutaraldehyde.....0.027%

Inert Ingredients:.....99.871%
Total.....100.00%

EPA Reg. No. 66171-107

[EPA Est. No. 66171-TN-001]
[EPA Est. No. 66171-CA-001]
[EPA Est. No. 61282-WI-01]
[EPA Est. No. 47000-IA-01]
(First letter of batch number indicates establishment)
Patent Number 5,891,922

KEEP OUT OF REACH OF CHILDREN
CAUTION

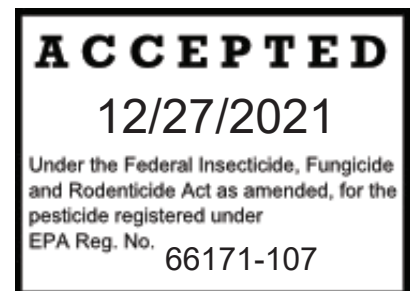
*{Note to Reviewer: In accordance with 40 CFR 156.68(d), all first aid statements, as prescribed, will appear on the front panel of the label.};
See (left) (back) (side) (right) panel(s) (of label) (below) for additional Precautionary Statements*

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
If you do not understand the label, find someone to explain it to you in detail."

Net Contents:

32 oz.
1 gal. (3.78L)
2.5 gal. (9.5L)
5 gal. (18.9L)
30 gal. (113.6L)
55 gal. (208L)

[Label No(s):] TBD
[Product Part No(s):] TBD
[UPC Code:] TBD



Manufactured by:
Preserve International
944 Nandino Blvd.
Lexington, KY 40511 U.S.A.

PRECAUTIONARY STATEMENTS
Hazards to humans and domestic animals

CAUTION

Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes or clothing. Prolonged or frequent repeated skin contact may cause an allergic reaction in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS: This product is toxic to birds, fish, and aquatic invertebrates. Caution should be used when applying indoors because pets may be at risk.

FIRST AID

If Swallowed:	<ul style="list-style-type: none">• 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.
If on Skin or Clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor immediately for treatment advice.

GENERAL INFORMATION

GENERAL INFORMATION: Have the product container or label with you when calling a poison control center or doctor or going for treatment. For non-emergency and general information on product use, etc., information pertaining to this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378, 8:00 am – 12:00 pm Pacific Standard Time, Monday – Friday; email: npic@ace.orst.edu; or website: www.npic.orst.edu. For emergencies, call the poison control center 1-800-222-1222.

NOTE TO PHYSICIAN

Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression and convulsions may be needed.

DESCRIPTION

[This product] is a multi-purpose disinfectant-cleaner when used according to disinfection directions. [This product] provides a broad spectrum kill of gram negative and gram positive microorganisms. [This product] provides effective disinfecting and cleaning in one operation when used according to disinfection directions.

[This product] 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 a 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.

[This product] 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, Ratite Facilities (Ostrich, Emu and Rhea Facilities), Calf Pens and associated Farm Vehicles, Veterinary Practices, Animal Care Facilities, and Animal Laboratories.

USE DIRECTIONS:

To disinfect and clean hard non-porous surfaces of walls, floors, tables, sinks, and garbage cans in non-animal areas associated with the sites noted (above) (on this label). Thoroughly clean all surfaces of visible soil. Apply the ready-to-use solution 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 reduce cross-contamination on treated surfaces into animal facilities, shoe baths containing one inch of ready-to-use solution must be placed at all entrances to buildings. Scrape waterproof shoes or boots and place in 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 apply using a high pressure or coarse spray system. Leave all treated surfaces exposed to solution visibly wet 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. This cleaning/rinsing step is only necessary on food contact surfaces.

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 visible soil, bedding, manure, caked-on dirt, spider webs, etc. from floors, surfaces, and 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 with ready-to-use solution.
- 6) Allow all treated areas to remain visibly wet 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 [this product] and allow to remain in contact for at least 10 minutes.
- 8) Ventilate buildings, vehicles, and other closed spaces. Do not house swine or other livestock until treatment has been 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. This cleaning/rinsing step is only necessary on food contact surfaces.

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) Empty all troughs, racks, and other feeding and watering appliances.
- 4) Remove all visible 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 animals.
- 5) Thoroughly clean all surfaces with soap or detergent and rinse with water.
- 6) Thoroughly saturate with ready-to-use solution using conventional spraying methods.
- 7) Allow all treated areas to remain visibly wet with this solution for at least 10 minutes.
- 8) 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 ready-to-use solution and allow to remain in contact for 10 minutes.
- 9) Ventilate buildings, vehicles, and other closed spaces. Do not house livestock or employ equipment until treatment has been set or dried.
- 10) 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. This cleaning/rinsing step is only necessary on food contact surfaces.

DIRECTIONS FOR USE IN POULTRY HOUSES:

- 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 ready-to-use solution.
- 6) Allow all treated areas to remain visibly wet with this solution for at least 10 minutes.
- 7) Ventilate building, coops, and other closed spaces. Do not house poultry or employ equipment until treatment has been set or dried.
- 8) 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. This cleaning/rinsing step is only necessary on food contact surfaces.

VETERINARY PRACTICE (CLINICS)/ANIMAL CARE FACILITIES/ANIMAL LABORATORIES/ANIMAL LIFE SCIENCE LABORATORIES/ANIMAL RESEARCH CENTERS/ANIMAL QUARANTINE AREAS/ZOOS/PET SHOPS/KENNELS/ANIMAL HUSBANDRY/ANIMAL BREEDING FACILITIES/BREEDING AND GROOMING ESTABLISHMENTS/TACK SHOPS - DISINFECTION DIRECTIONS:

For cleaning and disinfecting the following hard non-porous surfaces when used according to disinfection directions: equipment not used for animal food or water, utensils, instruments, cages, kennels, stables, stalls and catteries. 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 ready-to-use solution 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 set or dried.

*[This product] was found to be effective against the following organisms in the presence of 5% organic load:

[Avian Influenza A (H3N2)*] [ATCC VR-2072]	[Porcine Respiratory & Reproductive Syndrome Virus*] [(PRRS)] [Strain NVSL]
[<i>Aspergillus fumigatus</i>] [ATCC 36607]	[<i>Pseudomonas aeruginosa</i> *] [ATCC 15442]
	[<i>Salmonella</i>] [<i>choleraesuis</i> *] [<i>enterica</i> *] [ATCC 10708]
[<i>Escherichia coli</i> F18*]	[<i>Salmonella enteritidis</i> *] [ATCC 13076]
[Feline Calicivirus*] [Norovirus*] [ATCC VR-782]	[<i>Staphylococcus aureus</i> *] [ATCC 6538]
[<i>Haemophilus parasuis</i> *] [ATCC 19417]	[<i>Streptococcus equi</i> * (strangles)] [ATCC 33398]
[<i>Haemophilus somnus</i> *] [ATCC 700026]	[<i>Streptococcus equi sub Zooepideicus</i> *] [ATCC 43079]
[Porcine Circovirus Type 2*]	[<i>Streptococcus suis</i> *] [ATCC 43765]
[Porcine Epidemic Diarrhea Virus*] [Strain Colorado 2013]	[Vesicular stomatitis virus*] [ATCC VR-158]

Emerging Viral Pathogen Claims

{Note to Reviewer: These statements for claims against large non-enveloped, and/or enveloped emerging viral pathogens shall not appear on marketed (final print) product labels. The statements shall be made only through the following communications outlets: technical literature distributed exclusively to veterinarians, health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). }

Synergize RTU [this product] qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below:

Synergize RTU [this product] meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped viruses
- Large non-enveloped viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	<ul style="list-style-type: none">• Feline Calicivirus
Large non-enveloped virus	<ul style="list-style-type: none">• Feline Calicivirus

Synergize RTU [this product] has demonstrated effectiveness against viruses similar to *[name of emerging virus]* on hard, non-porous surfaces. Therefore, **Synergize RTU** [this product] can be used against *[name of emerging virus]* when used in accordance with the directions for use against *[name of supporting virus(es)]* on hard, non-porous surfaces. Refer to the *[CDC or OIE]* website at *[pathogen-specific website address]* for additional information.

[Name of illness/outbreak] is caused by *[name of emerging virus]*. **Synergize RTU** [this product] kills similar viruses and therefore can be used against *[name of emerging virus]* when used in accordance with the directions for use against *[name of supporting virus(es)]* on hard, non-porous surfaces. Refer to the *[CDC or OIE]* website at *[website address]* for additional information.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or 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 instructions, 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 containers greater than 5 gallons) Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ 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 containers 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 ¼ 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.

(For use with RTU packages only.)

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. 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.

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 ¼

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.

Alternate Brand Names:

(Synergize™ RTU)
(Synergize Cool™ RTU)
(Synergize NF™ RTU)
(Synergize NP™ RTU)
(Synergize NP-NF™ RTU)
(Synergize Orange™ RTU)
(Synergize Orange NF™ RTU)
(Companion™ RTU)

{Optional Marketing Statement(s) that may or may not be used on the label:}

(Preserve International is a wholly-owned subsidiary of Neogen Corporation.)
(Concentrate)
(Bactericidal)
(Cleaner-Disinfectant for use on hard nonporous surfaces when used according to disinfection directions)
(Veterinary Clinic Disinfectant)
(Animal Premise Disinfectant)
(For Veterinary Use)
(Multi-Purpose Cleaner and Disinfectant)
(Cleans, Disinfects, Deodorizes when used according to disinfection directions)
(Bleach-Free)
(For Farm Use)
(For Barn Use)
(Non-Damaging to Floors (Floor Finishes)
(Dual Active formulation provides broad spectrum activity against: viruses, bacteria, fungi)
(Phenol Free)
(Kills Influenza A virus on hard, nonporous surfaces)
(One-step cleaner-disinfectant on non-food contact surfaces when the Direction for Use for disinfection is followed)

Logo(s):

(«Synergize logo»)
(«Preserve International logo»)
(«Neogen logo»)
(«Neogen Flask icon»)
(«American Flag icon»)
(«PPE icon(s)»)

{Optional Warranty Statements:}

(DISCLAIMER: To the extent permitted by applicable law, Seller makes no representation or warranty, either express or implied, for results due to misuse, improper handling or improper storage of this material. Nor does Seller assume any responsibility for injury to persons, crops, animals, soil or property arising out of misuse, improper handling or improper storage of this material.)

{OR}

(LIMITED WARRANTY

To the extent permitted by applicable law, Preserve International and Neogen Corporation make no warranty concerning uses which extend beyond the use of the product under normal conditions in accord with the statements

made on this label. To the extent permitted by applicable law, Preserve International and Neogen Corporation shall not be liable for (1) any consequential, incidental or special damages related in any way to this product or its uses, or (2) any damages related in any way to resistance to pesticides.)

{OR}

(CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY)

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

To the extent permitted by applicable law Manufacturer and Seller warrant that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law this warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Manufacturer, and Buyer and User assume the risk of any such use. To the extent permitted by applicable law, MANUFACTURER AND SELLER MAKE NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESSED OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent permitted by applicable law, in no event shall Manufacturer or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF MANUFACTURER AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF THE MANUFACTURER OR SELLER, THE REPLACEMENT OF THE PRODUCT.

Manufacturer and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitations of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of Manufacturer.)

For non-emergency (e.g., current product information),
Call: **1-800-621-8829**