



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 22, 2016

Tamra Barrick
Regulatory Specialist
Preserve International
944 Nandino Blvd.
Lexington, KY 40511

Subject: Notification per PRN 98-10 –Updating address, emergency telephone number, Adding additional marketing statements, warranty statements and updating the Neogen logo(s) on the master label.
Product Name: ADVANTAGE™ 128
EPA Registration Number: 66171-2
Application Date: October 24, 2016
Decision Number: 523222

Dear Ms. Barrick,

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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.

If you have any questions, you may contact Lorena Rivas at 703-305-5027 or via email at rivas.lorena@epa.gov.

Sincerely,

A handwritten signature in blue ink, consisting of several overlapping, fluid strokes that form a cursive name.

for

Jacqueline Hardy, Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Notification Label

NOTIFICATION

66171-2

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

11/22/2016

ADVANTAGE 128

STAPHYLOCIDAL-PSUEDOMONACIDAL-BACTERICIDAL-FUNGICIDAL-TUBERCULOCIDAL- VIRUCIDAL* AT 1:128 DILUTION IN SOFT OR HARD WATER. FOR HOSPITAL, INSTITUTIONAL AND RESIDENTIAL USE

ACTIVE INGREDIENTS:

ortho-Phenylphenol	5.5%
ortho-Benzyl-para-Chlorophenol.....	3.0%
para-Tertiary-Amylphenol.....	2.0%
INERT INGREDIENTS:	89.5%

EPA Reg. No. 66171-2

EPA Est. No. 66171-TN-001
EPA Est. No. 66171-CA-001
EPA Est. No. 61282-WI-001
EPA Est. No. 47000-IA-001

(First letter of batch number indicates establishment)

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See [Inside] [Side] Panels for Additional Precautionary Statements

Net Contents:

55 gallons (208L)

Code: (NO.RL) RN.RA

Label No(s): TBD

Manufactured By:

Preserve International

944 Nandino Blvd.

Lexington, KY 40511

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: 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 (long-sleeved shirt and long pants, socks plus shoes, and chemical-resistant gloves such as water proof gloves). Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash it before reuse.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or public 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 sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear: long-sleeved shirt and long pants, socks and chemical-resistant shoes, goggles or face shield, and chemical-resistant gloves (such as barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or Viton selection category C). In addition, applicators and other handlers exposed to the fog during fogging applications, and until the fog has dissipated, and the enclosed area has been thoroughly ventilated activities must wear a full-face NIOSH-approved respirator that uses an N, R, or P series air purifying filter. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATION STATEMENTS

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Wash outside of gloves before removing. As soon as possible, wash thoroughly.

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 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.

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 for further treatment advice.

HOT LINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. **For 24-hour emergency information on this product, call 1-800-498-5743 (US & Canada) or 1-651-523-0318 (all other areas).**

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

DESCRIPTION: A synthetic detergent with broad spectrum kill of micro-organisms both gram positive and negative. For cleaning and disinfecting. Non-flammable and non-volatile in use dilutions. For use on electrically conductive floors. Dilutes clear at (1:128) in hot, cold, soft or hard water. Contains biodegradable detergent. Dilute as directed using standard measuring cup or jug pump. Do not mix with other cleaners.

Proven effective for hospital use by the following tests:
A.O.A.C. (Use Dilution)

The following tests run in conformance with A.O.A.C. Fifteenth Edition and all tests in presence of A.O.A.C., 1000 ppm water hardness and 5% organic soil. Dilution of 1:256.

Staphylococcus aureus
Pseudomonas aeruginosa

Salmonella choleraesuis
HIV-1 (AIDS virus)*

The following tests dilute clear at (1:128), unless otherwise specified, in hot, cold, soft or hard water of up to 500 ppm water hardness.

Salmonella typhosa
Staphylococcus aureus
Escherichia coli
Streptococcus hemolyticus
Streptococcus fecalis
Mycobacterium Tuberculosis BCG
Diplococcus pneumonia Adapt (Virucidal Test)* Influenza

Trichophyton interdigitale
Proteus vulgaris
Herpes Simplex WI-38
Type A2, Taiwan Strain-Asian Flu

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Recommended for disinfecting and deodorizing all pre-cleaned hard surfaces such as floors, walls, tile, stainless steel, aluminum, chrome, vinyl and glass surfaces. Suitable for use in Operating Rooms, Intensive Care, Emergency Areas, Nurseries, Patients' Rooms and Rest Rooms.

HOSPITAL AND RESIDENTIAL USE DIRECTIONS:

1. Recommended for use on pre-cleaned, hard, non-porous, inanimate surfaces.
2. To disinfect and deodorize floors, walls, and other similar hard surfaces, use 1 ounce Advantage 128 per gallon of water (dil 1:128). Apply with cloth, sponge, mop or mechanical spray device, making sure all surfaces are wetted thoroughly. Allow surfaces to remain wet for 10 minutes at 20°C.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

1. **PERSONAL PROTECTION:** Clean-up should always be done wearing protective latex gloves, gowns, masks and eye protection.
2. **CLEANING PROCEDURE:** Blood and other body fluids containing HIV must be thoroughly cleaned from surface and objects before application of Advantage 128.
3. **CONTACT TIME:** Leave surface wet for 10 minutes with 1 oz. per gallon use-solution.
4. **DISPOSAL OF INFECTIOUS MATERIAL:** Blood, body fluids, cleaning materials and clothing should be autoclaved and disposed of according to local regulations for infectious waste disposal.

Advantage 128 is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contact intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. Advantage 128 may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

GENERAL USE DIRECTIONS

1. Recommended for use on pre-cleaned hard, non-porous surfaces.
2. To disinfect and deodorize walls, floors, tables, drinking fountains, sinks, refrigerators, stoves, restroom fixtures, telephone booths, bird cages, kennels, and garbage cans. Apply a solution of 1 ounce Advantage 128 per gallon of water (dil 1:128). Apply with cloth, sponge, mop or mechanical 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.
3. For combs, brushes, razors, scissors, instruments, and rubber goods. All articles must be pre-cleaned to remove heavy soil and gross filth. Clean and rinse the lumens of hollow instruments before filling with solution. Wipe articles clean and soak for 10 minutes by immersion in a solution containing 1 ounce Advantage 128 per gallon of water (dil 1:128). Rinse all articles with clean water.
4. To disinfect fabrics such as sheets, linens, aprons and uniforms, first pre-clean to remove gross filth and heavy soil, then soak for 10 minutes in a solution containing 1 ounce of Advantage 128 per gallon of water (dil 1:128). Rinse in clean water and allow to dry.
5. Fresh solution should be prepared daily or when used solution becomes visibly dirty.

SHOEBATHS:

Shoebath containing one inch of freshly made disinfectant solution (1:128) should be placed at all entrances to buildings and hatcheries. Change the disinfectant solution in the bath daily or more often.

For all spray applications: Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers must be in area during application. Following application as a low-pressure or high-pressure spray, do not enter or allow others to enter the treated area until the sprays have dried.

For pour, pump, mop, and wipe applications: Do not apply this product in a way that will contact other persons. Only protected handlers may be in the area during application.

DIRECTIONS FOR USE IN POULTRY HOUSES, FARM PREMISES, SWINE PRODUCTION FACILITIES, EQUINE FACILITIES, VEAL BARN, RATITES FACILITIES AND CALF PENS:

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 litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
4. Empty all troughs, racks, and other feeding and watering appliances.
5. Thoroughly clean and saturate all surfaces with a solution of 1 oz. Advantage 128 per gallon of water (1:128), using conventional spraying methods. Allow to remain in contact for at least 10 minutes.
6. 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 in a solution of 1 oz. Advantage 128 per gallon of water (1:128). Allow to remain in contact for 10 minutes.
7. Thoroughly scrub all treated feed racks, troughs, automatic feeders, fountains, waterers, mangers, hatches, setters, trays, racks, sexing tables and delivery trucks with a solution of Advantage 128 at 1 oz. per gallon of water (1:128). Rinse with potable water before reuse.
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.

HATCHING EGG SANITIZER:

Advantage 128 is recommended for sanitizing hatching eggs at water temperatures of 78°F to 110°F and recommended dilution of 1 oz. per gallon of water (1:128) to be applied through immersion, automatic water system, foaming or fogging (wet misting) systems.

SANITIZING ROOMS USING A THERMAL FOGGER:

Fogging is to be used as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Close room off so fog is confined to room to be treated. Mix two (2) parts Advantage 128 to five (5) parts water (1 gallon Advantage 128 to 2.5 gallons of water). Insert the nozzle of the fogger through a suitable opening into the room. With the setting on maximum output, fog for one (1) minute to reach 4,000 cubic feet of space in the room with the thermal fogger.

Advantage 128 is recommended for use in fogging (wet mist) operations as an adjunct prior to acceptable manual cleaning and disinfecting of room surfaces. Use at a dilution of 1 ounce per gallon (1:128). Check with a Preserve International representative to determine an effective fogging schedule. Leave the room when fogging. In well-ventilated areas, such as hatcheries, only 10-15 minutes is necessary before re-entering. If used in a poorly ventilated area, allow at least 2 hours, or air thoroughly, before re-entry. Before fogging food processing areas, all food and food packaging items must be removed or carefully protected. Treated food contact surfaces must be thoroughly scrubbed with Advantage 128 at 1 ounce per gallon of water (1:128) and rinsed with potable water prior to reuse.

For fog applications: Thoroughly ventilate entire area following application. Do not enter, allow other persons to enter, house livestock, or use equipment in the treated area until ventilation is complete and any liquid has been absorbed, set, or dried. For entry into fogged areas before ventilation is complete and the fog has completely dissipated, all persons must wear personal protective equipment, including a full-face respirator, required in the precautionary statements section of this labeling for applicators and other handlers.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE:

Store in a cool and dry place. Do not transfer to another 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 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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. 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 ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. 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.

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 EXPRESS 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**

Optional Marketing Statement(s)/Graphic(s):

Preserve International is a wholly-owned subsidiary of Neogen Corporation.

«Preserve International logo»

«Neogen logo»

«Neogen Flask icon»