

66171-1

01/31/2007

1/4



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 31, 2007

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

Subject: **Advantage 256**
EPA Registration No. 66171-1
Application Dated: December 13, 2006
Receipt Date: December 28, 2006

Dear Mr. Gaumer:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with comment:

Proposed Amendment

- Revised labeling

General Comments

1. The use directions for Whirlpool and foot spa are partially consistent with Agency guidance, as outlined on <http://www.epa.gov/pesticides/factsheets/pedicure.htm>. Add the following instructions to the directions for use. "To disinfect **whirlpool foot spas, air-jet basins, "pipe-less" foot spas, and other circulating spas** turn the unit on to **circulate** the disinfectant for the entire contact time", not the one minute circulation, as interpreted from the proposed label.

2. Revise the ingredient statement to read:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Ortho-Phenylphenol.....	11.0%
Ortho-Benzyl-para-Chlorophenol.....	6.0%
Para-Tertiary-Amylphenol.....	4.0%
<u>Inert Ingredients</u>	<u>79.0%</u>
Total	100.0%

Note: On the proposed label change "jest" to "jets".

CONCURRENCES


SYMBOL							
SURNAME							
DATE							

Other Comments

A stamped copy of the accepted labeling is enclosed.

Should you have any questions or comments concerning this letter, please contact me by telephone at (703) 308-6422 or email address at: heyward.adam@epa.gov, or Renae Whitaker by telephone at (703) 308-7003 or email address at: whitaker.renae@epa.gov.

Sincerely,


 Adam Heyward
 Product Manager (34)
 Regulatory Management Branch II
 Antimicrobials Division (7510P)

Enclosure: (EPA stamped approved label)

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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 (1:256) 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 on hard, inanimate, non-porous surfaces for hospital use. 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 10% organic soil

Test Method	Dilution	Test Method	Dilution
Salmonella enteritidis #13076	1:256	*Adenovirus, type 2 #VR-84	1:256
Trichophyton mentagrophytes #9129	1:256	Staphylococcus aureus, methicillin resistant #25923	1:256
*Vaccinia virus #VR-1354	1:256	Staphylococcus aureus, gentamicin resistant #25923	1:256
*Avian Influenza Virus, #VR1354	1:256		

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

Test Method	Dilution	Test Method	Dilution
*HIV-1 (Aids Virus)	1:256	*Pseudorabies virus, Aujeszky Strain #VR-135	1:256
*Transmissible gastroenteritis virus - Purdue Strains #VR-763	1:256		

The following tests dilute clear at (1:256) in hot, cold, soft or hard water of up to 500 ppm water hardness

Test Method	Dilution	Test Method	Dilution
Salmonella typhosa #6539	1:256	Trichophyton Interdigitale #640	1:307
Staphylococcus aureus #14154	1:256	A.O.A.C. (Tuberculosidal Test)	
Streptococcus hemolyticus #9342	1:256	Mycobacterium tuberculosis BCG	1:256
Diplococcus pneumoniae #6303	1:256*	Adapt (Virucidal Test) influenza Type A2,	
Escherichia coli #11229	1:256	Taiwan Strain-Asian Flu	1:256
Proteus vulgaris #8427	1:256	Herpes Simplex WI-38	1:256
Streptococcus fecalis #8043	1:256	Pseudomonas aeruginosa PRD-10	1:256
Salmonella choleraesuis #10708	1:256	Staphylococcus aureus #6538	1:256

DIRECTIONS FOR USE:
It is in 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.

TUBERCULOCIDAL USE DIRECTIONS:
Thoroughly clean surface prior to application of product. Use 1/2 oz. **ADVANTAGE 256** per gallon of water. Apply with cloth, sponge, mop or mechanical spray device. Effective in 10 minutes at 20°C. Wipe dry and allow to air dry.

HOSPITAL 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 1/2 ounce **ADVANTAGE 256** per gallon of water (dil 1:256). 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. Wipe dry or allow to air dry.
3 Fresh solution should be prepared daily or when used solution becomes visibly dirty.

KILLS HIV ON PRECLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOODY/URINARY FLUIDS.
In health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES/OBJECTS SOILED WITH BLOODY/URINARY FLUIDS.

- PERSONAL PROTECTION:** When handling items soiled with blood or body fluids, use protective equipment such as disposable rubber gloves, gowns, masks or eye coverings.
- CLEANING PROCEDURE:** Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant.
- CONTACT TIME:** To kill HIV-1 (AIDS virus) a contact time of 10 minutes at room temperature must be allowed.
- DISPOSAL OF INFECTIOUS MATERIALS:** Blood and body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

EPA REG NO 66171-1

Manufactured by:
PRESERVE INTERNATIONAL
Zepher Cove, NV 89448 (800) 995-1607
www.preserveinternational.com Page 1 of 2

ACCEPTED FOR COMMENTARY
 FEDERAL REGISTER
 JAN 31 2007
 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the Pesticide, registered under EPA Reg. No. 66171-1

ADVANTAGE 256

CLEANER-DISINFECTANT-DEODORANT

STAPHYLOCIDAL-PSEUDOMONACIDAL-BACTERICIDAL - SALMONELLACIDAL-TUBERCULOCIDAL-FUNGICIDAL-VIRUCIDAL* AT 1:256 DILUTION IN SOFT OR HARD WATER. FOR HOSPITAL AND INSTITUTIONAL USE

ACTIVE INGREDIENTS:
 ortho-Phenylphenol 11.0%
 ortho-Benzyl-para-Chlorophenol 6.0%
 para-Tertiary-Amylphenol 4.0%
INERT INGREDIENTS: 79.0%

KEEP OUT OF REACH OF CHILDREN DANGER

See additional precautions on side panel

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE:
Store in 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 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.
Gallons or smaller: Do not reuse empty container. Rinse empty container thoroughly and discard in trash.
Metal: Triple rinse (or equivalent). Then offer for recycling or recondition, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

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. 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 by 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. 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.

USER SAFETY RECOMMENDATION STATEMENTS

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using 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.

Advantage 256 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 blood-stream 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 256** may be used to pre-clean 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, s'oves, restroom fixtures, telephone booths, bird cages, kennels, and garbage cans. Apply a solution of 1/2 ounce **Advantage 256** per gallon water (dil 1:256). 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 1/2 ounce **Advantage 256** per gallon of water (dil 1:256). 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 1/2 ounce of **Advantage 256** per gallon of water (dil 1:256). Rinse in clean water and allow to dry.
 5. Fresh solution should be prepared daily or when used solution becomes visibly dirty.
- SHOEBATHS:**
Shoecan containing one inch of freshly made disinfectant solution (1:256) 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 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.

PRECAUTIONARY STATEMENTS

HAZARD 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-sleeve 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 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, St. and chemical resistant shoes, Goggles or face shield, and Chemical-resistant gloves (such as barrier laminate, butyl rubber, nitril 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 dust/mist filtering respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix 14G), or a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any R,P, or HE prefilter. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washholes us. detergent and hot water. Keep and wash PPE separately from other laundry.

Batch No: _____ Net Contents: _____

DOT SHIPPING NAME
CORROSIVE LIQUID, BASIC, INORGANIC, N.O.S., (SODIUM HYDROXIDE), 8, UN3266, PGIII

NFPA HAZARD CLASSIFICATION

HEALTH	FIRE	REACTIVITY	SPECIFIC
2	1	0	ALK

3
4

ADVANTAGE 256

DIRECTIONS FOR USE IN POULTRY HOUSE, 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 1/2 oz **ADVANTAGE 256** per gallon of water (1:256), 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 1/2 oz **ADVANTAGE 256** per gallon of water (1:256). 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 256** at 1/2 oz per gallon of water (1:256). 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.

SHOEBATHS:

Shoebath containing one inch of freshly made **ADVANTAGE 256** solution (1:256) should be placed at all entrances to buildings and hatcheries. Change the disinfectant solution in the bath daily or more often

HATCHING EGG SANITIZER:

ADVANTAGE 256 is recommended for sanitizing hatching eggs at water temperatures of 78 degrees F to 110 degrees F and recommended dilution of 1/2 oz. per gallon of water (1:256) to be applied through immersion, automatic water system, foaming or fogging (wet misting) systems.

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 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.

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 one (1) part **ADVANTAGE 256** to five (5) parts water (1/2 gallon **ADVANTAGE 256** 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 256 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 1/2 ounce per gallon (1:256). 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 256** at 1/2 ounce per gallon (1:256) 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 the personal protective equipment, including a full-face respirator, required in the precautionary statements section of this labeling for applicators and other handlers.

Disinfecting Whirlpools & Foot Spas

Empty Whirlpool or Foot Spa. Thoroughly preclean and rinse interior surface to remove heavy soil and gross filth, making sure to clean under any rim and in crevices. Remove screen and all debris trapped behind the screen. Preclean and rinse screen and inlet. Use 1/2 oz Advantage 256 per gallon of water (1:256). Turn jet on for 1 minute, then turn off and let soak for 9 minutes. Drain and rinse all surfaces with clean water.

Disinfecting Tanning Beds

Preclean and rinse to remove heavy soil and gross filth from surface. Apply a solution of 1/2 oz Advantage 256 per gallon of water (1:256) with a cloth, sponge or mechanical coarse spray device, making sure all surfaces are wetted thoroughly. Allow surface to remain wet for 10 minutes, then rinse with clean water

Manufactured by:

PRESERVE
INTERNATIONAL

Zepher Cove, NV 89448 • (800) 995-1607

EPA REG NO: 66171-1
EPA EST NO: 66171-TN-001

ACCEPTED
with COMMENTS
EPA Letter # 66171-1

JAN 31 2007

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this pesticide is amended, for the pesticide registered under EPA Reg. No. 66171-1

4/17