

41130 100-11-3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 02 1995

Mr. Gary E. Gaumer
 Preserve International
 2524 Industrial Rowe
 Turlock, CA 95380

Dear Mr. Gaumer:

Subject: Advantage 128
 EPA Registration No. 66171-2
 Your Amendment Dated August 29, 1994
 and Submission Dated May 17, 1995

This is in response to your request to amend this registration to include a claim of effectiveness against HIV (Aids Virus) on the label.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended is acceptable provided that you make the following revisions before you release the product for shipment bearing the amended labeling.

- Under General Use Directions, item 3: the dilutions for fogging and treating food contact surfaces are incorrect. The instructions require one-half ounce of Advantage-128 per gallon, yet the numerical fractions of (1:128) is equivalent to one ounce per gallon.

A stamped copy of the label is enclosed for your records. Submit one copy of the final printed label.

Efficacy Data:

The submitted efficacy data (MRID No. 433535-01) appear adequate to support effectiveness of the product as a virucide when used on hard non-porous surfaces against HIV (Aids Virus) when diluted with 1011.4 ppm AOAC hard water to make a 1:128 solution in the presence of 5% blood serum for a contact time of ten minutes at 23°C.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

If you have any questions, please call Marianne Clark at
(703) 305-7879.

Sincerely yours,



Ruth Douglas
Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

flammable and non-volatile in use dilutions. For use on electrically conductive floors. Dilute clear at (1:128) in hot, cold, soft or hard water. 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. (See Dilution)

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

TEST METHOD	DILUTION	TEST METHOD	DILUTION
Staphylococcus aureus #6636	1:128	Salmonella choleraesuis #16768	1:128
Pseudomonas aeruginosa PRD-10 #15442	1:128	HRV-1 (AIDS VIRUS)*	1:128

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

TEST METHOD	DILUTION	TEST METHOD	DILUTION
Salmonella typhosa #6538	1:128	Tychophyton lanthiphala #640	1:154
Staphylococcus aureus #14154	1:128	A.O.A.C. (Tuberculocidal Test)	
Staphylococcus hemolyticus #6342	1:128	Mycobacterium Tuberculosis 80G	1:128
Diphtheria pneumoniae #6303	1:128	Adapt (Mucoid Test)* Influenza	
Escherichia coli #11229	1:128	Type A2, Taiwan Strain-Axin Ph	1:128
Proteus vulgaris #6427	1:128	Hepes Simplex 98-38	1:128
Streptococcus faecalis #6940	1:128		

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 equipment, chrome, wax and glass surfaces. Suitable for use in Operating Rooms, Intensive Care, Emergency Areas, Nurseries, Patients Rooms and Rest Rooms.

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 ounce Product Disinfectant per gallon of water (all 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 ON SURFACE OBJECTS SOLID WITH BLOOD/BOOY 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 decontaminated and disposed of according to local regulations for infectious waste disposal.

GENERAL USE DIRECTIONS:

1. Recommended for use on pre-cleaned, hard surfaces.
2. To disinfect and deodorize walls, floors, toilets, drinking fountains, sinks, refrigerators, stoves, stainless fixtures, telephone booths, 17 d cages, handrails, and garbage cans. Apply a solution of 1 ounce Product Disinfectant per gallon water (all 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. Advantage-128 is recommended for use in logging (not mixing) operations on an infected either preceding or following regular cleaning and disinfecting procedures. Use at a dilution of 1/2 ounce per gallon (1:128). Check with a local representative to determine effective logging schedule for particular use sites. Leave the room when logging. In well ventilated areas, such as hatcheries, only 10 to 15 minutes is necessary before re-entry. If used in a poorly ventilated area, allow at least 2 hours, or air thoroughly, before re-entry. Before logging in local 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 1:128 or per gallon (1:128) and rinsed with potable water prior to reuse.
4. For awlins, brushes, rags, sponges, instruments, and rubber goods. All articles must be pre-cleaned to remove heavy soil and gross film. Immerse and clean the surfaces of hollow instruments before filling with solution. Wipe articles clean and soak for 10 minutes by immersion in a solution containing 1 ounce Product Disinfectant per gallon water (all 1:128). Rinse all articles with clean water.
5. To disinfect fabrics such as sheets, linens, aprons and uniforms, first pre-clean to remove gross film and heavy soil, then soak for 10 minutes in a solution containing 1 ounce of Product Disinfectant per gallon of water (all 1:128). Rinse in clean water and allow to dry.

ADVANTAGE 128

CLEANER-DISINFECTANT-DEODORANT

STAPHYLOCIDAL-PSEUDOMONACIDAL-BACTERICIDAL-FUNGICIDAL-TUBERCULOCIDAL-VIRUCIDAL *

1:128 DILUTION IN SOFT OR HARD WATER. FOR HOSPITAL AND INSTITUTIONAL USE.

ACTIVE INGREDIENTS:

ortho-Phenylphenol.....	5.5%
ortho-Benzyl-para-Chlorophenol.....	3.0%
para-Tertiary-Amylphenol.....	2.0%

INERT INGREDIENTS:..... 89.5%

DANGER: KEEP OUT OF REACH OF CHILDREN

See First Aid statement and additional precautions on side panel.

EPA Registration No.: 56171-2

EPA Establishment No.: 66171-TN-001

Net Contents: _____

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 02 1995

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



PRESERVE
INTERNATIONAL

Zephyr Cove, NV 89448

Exclusively Manufactured By

PRESERVE INTERNATIONAL ZEPHYR COVE, NV 89448

Telephone (800) 995-1607