

PM31

32970-3

10/7/99

1 of 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

American Cleaning Solutions  
Div. Of American Wax Company  
39-30 Review Avenue  
Long Island City, NY 11101

OCT 07 1999

Subject: AD-BAC 4227  
EPA Registration No. 32970-3  
Amendment Dated April 8, 1999

Attn: Harold Schwartz  
Vice-President

The amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, is acceptable with comments provided for labeling.

The submitted data demonstrate the effectiveness of this product as a virucide against HIV-1 (AIDS virus) on hard, non-porous surfaces in the presence of organic soil (5% serum) when applied at a dilution of 1:64 in 459 ppm hard water at room temperature (20-25 degree centigrade) with a contact time of two minutes.

Regarding the labeling comments, on the left panel, change "Hard surface disinfection..." to read "Hard non-porous surface disinfection..." Under "Directions For Use" change the following:

- a. Change "use at 2 ounces..." to read "use 2 ounces..."
- b. Change the statement "the product is fungicidal against pathogenic fungi" to read "the product is fungicidal against pathogenic fungi, Trichophyton mentagrophytes".
- c. Change the statement "apply to walls, floors and other hard surfaces" to read "apply to walls, floors and other hard non-porous surfaces".
- d. Change the statement "surfaces must remain wet for 10 minutes to read "Surfaces must remain wet for 10 minutes and allow to air dry".
- e. Change the statement "AD-BAC 4227 when used on environmental inanimate hard surfaces... to read "AD-BAC 4227 when used on environmental inanimate hard non-porous surfaces..."

This product must not be used to clean the following food contact surfaces: utensils, glassware and dishes. No Restricted Use Classification is recommended.

CONCURRENCES

SYMBOL	7510C						
SURNAME	Jones						
DATE	10-7-99						

OFFICIAL FILE COPY

PRECAUTIONARY STATEMENTS: Corrosive. Causes irreversible eye damage or skin burns. Do not get in eyes, on skin or clothing. Wear goggles or face shield. Wear protective clothing and rubber gloves. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT: 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 by a poison control center or doctor.

IF ON SKIN: 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 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 poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN:

The following "Note to Physician" statement is required for the subject product:

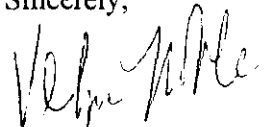
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

This labeling is derived from the term "corrosive" found on the submitted product label and the Label Review System. You may retain the statement "measures against circulatory shock, respiratory depression and convulsion may be needed."

A stamped copy of the label is enclosed for your records. Submit one (1) copy of the final printed label before this product is released for shipment.

If you have any questions concerning the comments in this letter, you should contact Zenobia Jones at (703) 308-6198.

Sincerely,



Velma Noble  
Product Manager 31  
Regulatory Management Branch 1  
Antimicrobial Division (7510C)

**AD-BAC 4227** is a cleaner and disinfectant designed for institutional use such as hospitals, nursing homes and institutions where housekeeping will be of prime importance in controlling the hazard of Cross-Contamination. Hard surface disinfection can help in this control and can provide the assurance you need in this area, when used as directed for use on floors, walls, sink tops, garbage pails, telephones, rest rooms, bed pans and operating rooms. Effective against *Staphylococcus aureus*, *Salmonella choleraeuis* and *Pseudomonas aeruginosa*. Also effective against pathogenic fungi, *Trichophyton inter-digitale*.

**PRECAUTIONARY STATEMENTS  
HAZARDOUS TO HUMANS AND  
DOMESTIC ANIMALS.**

**DANGER:** Keep out of reach of children. Cor-rosive causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Protect eyes and skin when handling. Harmful if swallowed. Avoid contamination of food.

**FIRST AID:** In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash all contaminated clothing before reuse. If swallowed, promptly drink a large quantity of milk, egg whites, gelatin solution or, if these are not available, drink large quantities of water. Call a physician immediately.

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

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

**DIRECTIONS FOR USE:**

It is a violation of Federal Law to use this product in a manner inconsistent with the labeling.

Use at 2 ounces per gallon. This product will be effective against *Pseudomonas aeruginosa* PRD-10 at this level. This has been substantiated by the AOAC Use Dilution Confirmation Test. At this level, the product is fungicidal against pathogenic fungi. For best results, use **AD-BAC 4227** with a cloth or mop and apply to walls, floors and other hard surfaces.

Surfaces must remain wet for 10 minutes.

For heavy soil or organic matter, a precleaning step is required.

Do not reuse empty container. Rinse thoroughly with water and discard it in trash.

**AD-BAC 4227** when used on environmental inanimate hard surfaces at 2 ounces per gallon of water is effective against influenza A<sub>2</sub>, Herpes Simplex, Adenovirus type 2 and Vaccinia Viruses.

**VIRUCIDAL\* ACTIVITY** - At 2 ounces per 1 gallon in the presence of 5% blood serum and 400 ppm of hardness for a 2 minute contact time this product was found to be effective against HIV-1 (AIDS Virus).

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

Effective against HIV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care 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).

**PERSONAL PROTECTION:** Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.

**AD-BAC 4227**  
**Cleaner • Disinfectant**  
**Deodorizer • Fungicide**  
**Virucide\***

Designed for Hospital and Institutional use.

**Active Ingredients:**

n-Alkyl (60% C<sub>14</sub>, 30% C<sub>16</sub>, 5% C<sub>12</sub>, 5% C<sub>18</sub>)  
dimethyl benzyl ammonium chlorides.....2.25%  
n-Alkyl (68% C<sub>12</sub>, 32% C<sub>14</sub>)  
dimethyl ethylbenzyl ammonium chlorides.....2.25%

Inert Ingredients.....95.50%  
100%

EPA Reg. No. 32970-3  
EPA EST. 32970 NY 01

**DANGER**

KEEP OUT OF REACH OF CHILDREN. SEE LEFT SIDE  
PANEL FOR ADDITIONAL PRECAUTIONARY AND  
FIRST AID STATEMENTS.

Sold By:

**AMERICAN** Cleaning Solutions  
Division of American Wax Company, Inc.

39-30 Review Ave  
Long Island City, New York 11101  
(718) 392-8080

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

OCT - 7 1999

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 32970-3

CLEANING must be thorough application of DISPOSAL other body fluids according to waste disposal CONTACT contact time and bacteria.

**STORAGE:** Store in original container, prevent leaking, transport and disposal. Avoid cross-contamination. Keep in original container. Triple rinse (or more) before reuse or by other product. **PESTICIDE** Wastes resulting from use on site or at a Pesticide waste management law. If these wastes are not managed according to instructions, contact your local agency or the regional office.

AUTHORITY INSP

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