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45631-3

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FEB 06 1989

Alcide Corporation
One Willard Road
Norwalk, CT 06851

Attention: Pamela Nicholas
Manager/Regulatory Affairs

Gentlemen:

Subject: Alcide® Brand Exspor™ 4:1:1 Sterilant Disinfectant (Part 1 Base Concentrate)
EPA Registration No. 45631-3
Your Amendment Application Dated June 23, 1988

The submitted data meet the requirements to support effectiveness of the product as a virucide against HIV-1 (AIDS virus) on hard, nonporous surfaces in the presence of a moderate amount of organic soil (10% blood serum) when used at a 4:1:1 dilution (14 days aged activated solution) in 400 parts per million CaCO₃ hard water for a contact time of 30 seconds at room temperature (20 to 25 °C).

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
 - a. The contact time of 30 seconds employed for efficacy testing against HIV-1 does not correlate with the contact time of 3 minutes supported in previously accepted efficacy data for disinfection and the last accepted labeling for this product. Therefore, if a claim for shorter contact time is made for HIV-1, a statement similar to the following will be required "Although efficacy at a 30 seconds contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 1 to 3 minutes contact time for disinfection against all of the organisms claimed."

57152:I:Douglas:LK-6:KENCO:12/23/88:1/4/89:SG:vo:rw

CONCURRENCES

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| SURNAME | | | | | | | |
| DATE | | | | | | | |

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- b. Label reference to "HIV (AIDS virus)" must be revised to read "HIV-1 (AIDS virus)."
 - c. The labeling requirements for antimicrobial pesticides used on hard surfaces against HIV-1 (AIDS virus) are indicated on the enclosure. It is important to note that featured statements/phrases, emphasized/enlarged lettering, special graphics, or any product name that employs the term "AIDS" are not acceptable, as indicated in item 2. Special instructions for this use pattern must be provided in the format indicated in item 4 of this enclosure.
 - d. Refer to our letters dated January 27 and August 18, 1988 for additional labeling requirements.
2. Submit five (5) copies of your final printed labeling before you release the product for shipment. Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions in this regard, please contact Ms. Ruth Douglas at (703) 557-3842.

Sincerely yours,



Jeff Kempter
Product Manager (32)
Antimicrobial Program Branch
Registration Division (TS-767C)

Enclosures

DM32

45631-3

BASE
CONCENTRATE

Alcide[®]
Brand

EXSPORTM
4:1:1

**STERILANT-
DISINFECTANT**

FOR MEDICAL ENVIRONMENTS
FOR USE WITH EXSPOR[™] ACTIVATOR 4:1:1

SPORICIDAL-BACTERICIDAL-VIRUCIDAL-FUNGICIDAL-
TUBERCULOCIDAL-PSEUDOMONACIDAL

STERILIZING LEVEL—Kills dried spores of *C. sporogenes* and *B. subtilis* on environmental surfaces in 6 hours.

DISINFECTING LEVEL—Kills all bacteria including *Pseudomonas aeruginosa* and *Mycobacterium sp.*, pathogenic fungi and viruses*[†] in 1-3 minutes (SEE DIRECTIONS FOR USE).

* Kills Influenza Virus Type A2 (Hong Kong); Herpes Simplex Virus Types I and II; Poliovirus Type I; Coxsackievirus; Adenovirus Type 2; Echovirus Type II; Vaccinia Virus and Vesicular Stomatitis Virus (VSV).

†Currently, there is no established test for hepatitis viruses.

| | |
|---|----------------|
| Active Ingredients: Sodium Chlorite | 1.37% |
| Inert Ingredients: | 98.63% |
| TOTAL | 100.00% |

**CAUTION: See Back Panel
CONTENTS 1 QT.**

Accepted
American
Hospital
Association

ACCEPTED
WITH COMMENTS
by EPA on 2/6/89 Dated:

FEB 06 1989

45631-3

LOT NO.

Insert #1

Alcide
CORPORATION

Norwalk, Connecticut 06851
U.S. Patent No. Re. 31,779
Other Patents Pending
Foreign Patents
EPA Reg. No. 45631-03
EPA Est. No. 45631CT01

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use #2

INSERT #1-Add Phrase" on environmental surfaces"
INSERT #2-Add Line: " Inactivates HIV (AIDS virus) within 30 seconds."

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Base Concentrate

EXSPOR™ Sterilant-Disinfectant is recommended for use in schools, hospitals and medical, dental, industrial and institutional facilities to eliminate human health-related microorganisms on equipment and hard, non-porous surfaces.

DIRECTIONS FOR USE

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

ACCEPTED
MICROBIOLOGICAL TESTS
IN LABORATORY

PREPARATION:

1. Measure 1 part EXSPOR Base Concentrate (Part 1) into a clean, empty, NON-METALLIC container.
2. Add 4 parts cool tap water (at or below 25°C).
3. Add 1 part EXSPOR Activator Concentrate (Part 2) and stir.

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DO NOT mix concentrate directly. The final solution may appear colorless or pale yellow. Variations in local water hardness may result in darker color and/or stronger odor. Deionized or distilled water may be substituted to minimize these effects.

Moderate amounts of organic load, such as soil, will not lower the efficacy of EXSPOR solutions. However, to ensure best results, surfaces should be rinsed and, if possible, equipment dismantled and rinsed free of heavy soil and gross debris. Hollow objects must be flushed and filled. User judgement and standard practice may require rinsing with sterile water prior to drying.

DISINFECTION: Prepare EXSPOR solution as described above. Disinfection is not affected by water hardness up to 400 ppm (calculated as CaCO₃).

Once mixed, the product has an effective shelf-life for disinfection of 14 days and may be used as a stock solution for up to 14 days. Discard used solution after each day's use. EXSPOR solution will inactivate HIV (AIDS virus) in 30 seconds. It will also inactivate bacteria, (including M. tuberculosis), fungi and viruses in 3 minutes for up to 14 days after preparation.

If Exspor solution is freshly prepared and used within 24 hours, viruses, pathogenic fungi and M. tuberculosis are inactivated in 1 minute and bacteria in 2 minutes.

Soaking is the best method of application. However, the solution may be sprayed or wiped on by any convenient means (mop, cloth, sponge, etc.) USE IN A WELL VENTILATED AREA. The surface should be thoroughly wet with solution. To minimize potential for oxidation or corrosion, a contact time of 3 minutes on metal surfaces or equipment should not be exceeded.

STERILIZATION: Prepare EXSPOR solution as described above. For sterilization, EXSPOR sterilizing solution should be used within 24 hours of preparation. Items should be immersed in the solution for 6 hours. Aseptic transfer of the treated articles to a sterile, enclosed container for air drying is recommended. Discard used solution after each day's use. After the first 24 hours, unused remaining solution may be used for disinfection.

NOTE: EXSPOR solution may be safely used on most plastics, and rubber, ceramic, epoxy and glass. Never soak items in metal vessels. Prolonged or repeated exposure will oxidize metals, including aluminum and stainless steel. Do not use on copper, brass or bronze. Do not apply to surfaces containing residues from bleach, strong acids, or other chemicals.

STORAGE AND DISPOSAL

Store unmixed concentrates in a cool, dark, dry place in the original containers. Always replace cover. Keep upright. Thoroughly wash empty concentrate containers with water and discard in a safe place. Do not reuse containers. Used and outdated EXSPOR solution may be flushed down the drain. Prepared EXSPOR solution should be stored in a cool, dark place.

ACCEPTED
with COMMENTS
in EPA Form 8600

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WARRANTY LIMITATION AND DISCLAIMER

ALL EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR PARTICULAR PURPOSE OR OTHERWISE ARE EXPRESSLY EXCLUDED. THERE ARE NO WARRANTIES WHICH EXTEND BEYOND THE DESCRIPTION ON THE FACE HEREOF. In the event this product or its performance shall not conform with the description on the face hereof, Manufacturer's sole obligation shall be to refund to Purchaser the purchase price hereof, or to replace this unit of product with a conforming unit at Seller's option. Purchaser agrees that such refund or replacement shall be Purchaser's sole remedy for claim arising out of the purchase or use of this product. Before using this product, user shall determine the suitability of the product for its intended purpose and user assumes all risk and liability in connection therewith. User shall be responsible for its compliance with all federal, state and local laws and regulations regarding the product and its use, storage, handling and disposal.