

FEB 06 1989

Alcide Corporation
One Willard Road
Norwalk, CT 06851

Attention: Pamela Nicholas
Manager/Regulatory Affairs

Gentlemen:

Subject: Alcide® Brand LD™ 10:1:1 Disinfectant
EPA Registration No. 45631-15
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 25:1:1 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							
SYMBOL							
SURNAME							1 of 6
DATE							

- 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 letter dated August 19, 1988 for an additional labeling requirement.
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

2 of 6

DRAFT

BASE
CONCENTRATE

Alcide®

Brand

LD™

10:1:1

DISINFECTANT
FOR MEDICAL ENVIRONMENTS
FOR USE WITH LD™ ACTIVATOR 10:1:1

LD Disinfectant kills bacteria, fungi and viruses*† on environmental surfaces. LD is effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis* and *Mycobacterium tuberculosis* in organic soil in 1-3 minutes (SEE DIRECTIONS FOR USE). It is supplied as a concentrate for economy and convenience.

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

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

Active Ingredients: Sodium Chlorite	2.73%
Inert Ingredients:	97.27%
TOTAL	100.00%

CAUTION: See Back Panel

CONTENTS 1 QT.

ACCEPTED
with COMMENTS
in EPA Label Draft:

FEB 06 1985

Unit: _____
For: _____
as a: _____
to: _____
Total: _____

45631-15

LOT NO.

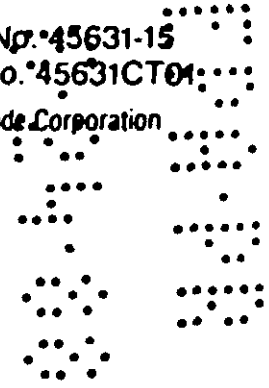
Alcide®
CORPORATION

Norwalk, Connecticut 06851

U.S. Patent No. Re. 31,779
Other Patents Pending
Foreign Patents

EPA Reg. No. 45631-15
EPA Est. No. 45631CT01

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INSERT #1-Add Line: Inactivates HIV (AIDS virus) within 30 seconds.

30/6

DRAFT

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 06 1988

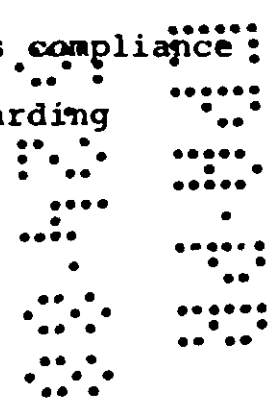
Under the terms of the Title
EPA's consent to the Act
and the consent to the title
of the Act, EPA Reg. No.
45631-15

STORAGE AND DISPOSAL

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

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.



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LD Base Label

LD Disinfectant is recommended for use in schools, hospitals and medical, industrial and institutional facilities to disinfect equipment, glassware, incubators, 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.

PREPARATION:

1. Measure 1 part LD Base Concentrate (Part 1) into clean, empty, non-metallic container.
2. Add 10 parts cool tap water (at or below 25°C).
3. Add 1 part LD Activator Concentrate (Part 2) and stir.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

FEB 06 1989

USE OF THIS PRODUCT IS LIMITED TO THE USES SPECIFIED ON THE LABEL. FOR OTHER USES, CONTACT THE EPA REGIONAL OFFICE. EPA REG. NO. 45631-15

DO NOT mix concentrates directly. The final solution may appear colorless or pale yellow. Product performance is not affected by water hardness up to 400 ppm (calculated as CaCO₃) however, variations in local water supply may result in a darker color and/or stronger odor. Deionized or distilled water may be substituted to minimize these effects.

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

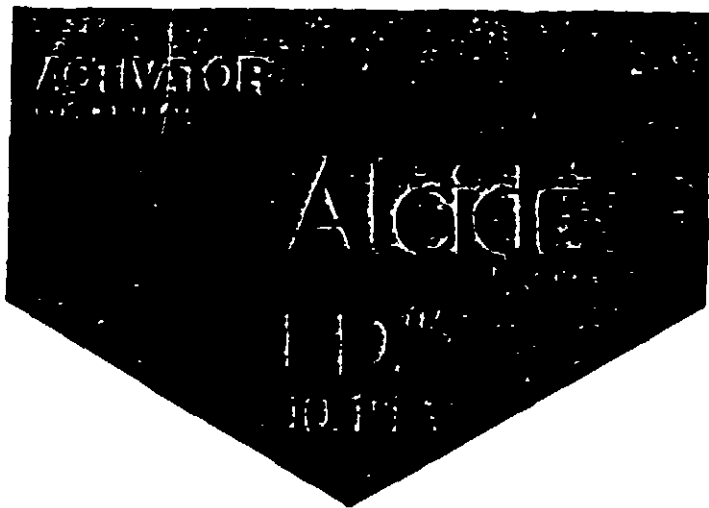
If LD solution is freshly prepared and used within 24 hours, bacteria, viruses, pathogenic fungi and M. tuberculosis are inactivated in 1 minute.

Moderate amounts of organic load, such as soil, will not lower the efficacy of LD 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 judgment and standard practice may require rinsing with sterile water prior to drying.

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 or equipment 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.

NOTE: LD disinfectant may be safely used on most plastics, 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 with residues from bleach, strong acids, or other chemicals.

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DISINFECTANT
FOR MEDICAL ENVIRONMENTS
FOR USE WITH LD™ BASE 10:1:1
Contains 15.1% Organic Acid

Follow directions for mixing, use, storage and disposal on the LD BASE label. Use only according to label directions. DO NOT MIX BASE AND ACTIVATOR DIRECTLY. Wash measuring container before reuse.

CAUTION: See Back Panel

CONTENTS 1 QT.

LOT NO.

Alcide®
CORPORATION

Norwalk, Connecticut 06851

U.S. Patent No. Re. 31,779
Other Patents Pending
Foreign Patents

~~EPA Reg. No. 45691-15~~
~~EPA Est. No. 45691GT01~~

ACTIVATOR
CONCENTRATE
LD™ 10:1:1
Disinfectant



Alcide®
Brand

This caution statement refers only to the unmixed LD Activator Concentrate

WARNING—HAZARDS TO HUMANS

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear goggles or face shield. Wash thoroughly with soap and water after handling.

First Aid: If in eyes, hold eyelids open and flush with a steady, gentle stream of water for 15 minutes.

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