

7551-15 P1122

MAY - 7 1985

Alcide Company Limited Partnership
125 Main Street
Westport, CT 06880

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Gentlemen:

Subject: Alcide LD 10:1:1 for Medical Environments
EPA Registration No. 45631-15
Your Submission of January 23, 1985

The submitted Phenol Resistance data for Mycobacterium tuberculosis fulfill the data request indicated in our letter of December 20, 1984.


The amendment referred to above, submitted in connection with registration under FIFRA sec. 3(c)(7)(A) is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:
 - a. On the Alcide LD label, the 440 ppm water hardness claim must be revised to read 400 ppm.
3. Submit five (5) copies of your final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). 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.

Sincerely yours,


A. E. Castillo
Product Manager (32)

Disinfectants Branch
Registration Division (78-767C)

SYMBOL ▶						
SURNAME ▶						
DATE ▶	Enclosure					

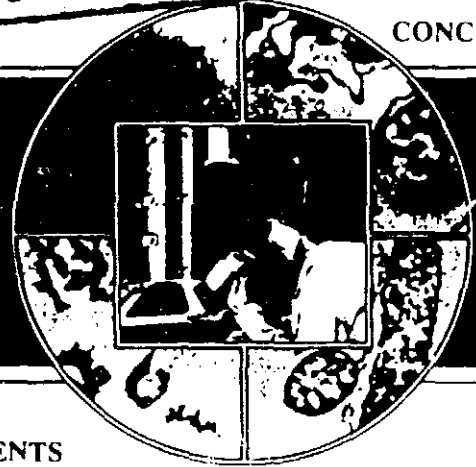
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BASE

CONCENTRATE

ALCIDE LD™

ALCIDE
LD™
10:1:1



ALCIDE LD Disinfectant is recommended for use in hospitals, clinics, dental offices and other medical facilities for disinfecting instruments, glassware, etc.

DIRECTIONS FOR USE

- It is a violation of Federal Law to use this product in a manner inconsistent with the label directions.
- Mix with water as follows: Dilute 1 part B with 10 parts cold tap water (below 30°C), then add 1 part A to make 12 parts total. LD Base must be used with LD Activator. Mix Base and Activator directly. Rinse measuring devices. Example: Dilute 100 ml Base into 1000 ml water to make 1200 ml total. Disinfectant solution may appear cloudy.
 - Although performance of the product is not affected by up to 440 ppm (calculated as CaCO₃), variations in water hardness result in a darker color or stronger odor. Do not be substituted to minimize these effects. Once mixed, the product has an effective shelf life and may be used as a stock solution for up to 14 days. Do not use after 1 day's use.
 - Moderate amounts of organic soil will not affect the Disinfectant. To ensure best results, however, instruments should be dismantled, if possible, and rinsed free of blood. The lumen of any hollow instrument must be flushed.
 - Soaking is the best method of application. Instruments may be sprayed or wiped on by any convenient means (e.g., brush).
 - The surface, instrument, or apparatus should be rinsed with solution.
 - To inactivate bacteria, viruses, pathogenic fungi, and protozoa, apply for 3 minutes.
 - If solution is freshly prepared with deionized water and used within 24 hours, bacteria, viruses, and tuberculosis are inactivated within 1 minute.
 - Rinsing is not necessary after disinfecting.
 - LD Disinfectant may be safely used on 300 series stainless steel, plastic, rubber, ceramic and glass. P-1 aluminum and carbon steel. Do not use on copper alloys.

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

LD kills bacteria, fungi and viruses*† on environmental surfaces. LD is effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella choleraesuis* in organic soil in (1). 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 Ingredient: Sodium Chlorite	2.73%
Inert Ingredients	97.27%
TOTAL	100.00%

U.S. Patent No. Re 31,779 EPA Reg. No. 45631-15
Other Patents Pending Contents: 1 Qt. EPA Est. No. 45631 CT01

Foreign Patents
Alcide ALCIDE CORPORATION
Norwalk, CT 06851

LOT NO

(1) 1-3 minutes (SEE DIRECTIONS FOR USE)

ACCEPTED
with COMMENTS
in EPA Letter Date:

MAY 7 1985

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 45631-15

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The following refers to Base Concentrate only:

CAUTION - HAZARDS TO HUMANS

Causes eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling.

First Aid: If in eyes, flush eyes with plenty of water. Call a physician if irritation persists.

STORAGE AND DISPOSAL

Store concentrates in a cool, dry place in the original containers. Always replace covers. Keep upright. Wash empty concentrate containers thoroughly with water and discard in a safe place. Do not reuse empty containers.

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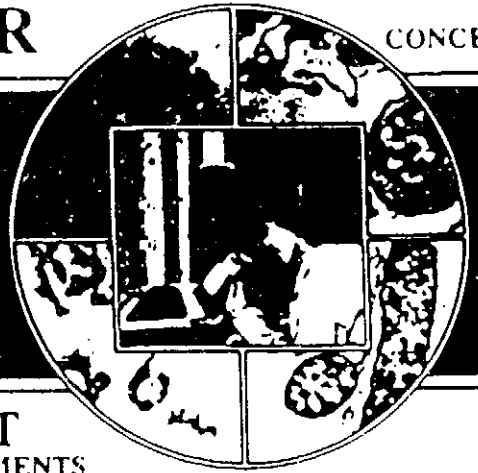
ACTIVATOR

CONCENTRATE

ALCIDE LD™

10:1:1

ALCIDE
LD™
10:1:1



DISINFECTANT

FOR MEDICAL ENVIRONMENTS

FOR USE WITH ALCIDE 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.

The following refers to Activator Concentrate only:

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.

LOT NO.



Alcide®

Contents: 1 Qt.
ALCIDE CORPORATION
Norwalk, CT 06851

U.S. Patent No. Re 31,779
Other Patents Pending
Foreign Patents
EPA Reg. No. 45631-15
EPA Est. No. 45631CT01

ALCIDE LD™
with 10:1:1 BASE
EPA Reg. No. 45631-15

MAY 1985

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, this product is registered under EPA Reg. No.

45631-15