

PM 32

45631-18

9-29-98

10/3



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7504C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

45631-18

Date of Issuance:

SEP 29 1998

NOTICE OF PESTICIDE:

- Registration
- Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

SD-3 Disinfectant System

Name and Address of Registrant (include ZIP Code):

Alcide Corporation
8561 154th Avenue, NE
Redmond, Washington 98052

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) 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; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

- a. Revise the EPA Registration Number to read, "EPA Reg. No. 45631-18".
- b. On the left front panel, place the heading "Precautionary Statements" and "Hazards to Humans and Domestic Animals" above the word Caution: Harmful if swallowed.
- c. Revise the statement "NOTE: SD-3 disinfectant may be used on formica..." to read: "NOTE: SD-3 disinfectant may be used on hard, non-porous surfaces such as formica..."

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Signature of Approving Official:

Robert S. Brennis, PM 32

Date:

SEP 29 1998

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- d. Add a period to the percentage of active and inert ingredients on the label (00.51% and 99.49%, respectively).

3. Submit two copies of the revised final printed label for the record.

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 constitutes acceptance of these conditions.

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

A handwritten signature in black ink, appearing to be 'RIB', is written below the text.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 29 1998

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

45631-18



READY TO USE



MIXES ON DEMAND



READY TO USE



Lot No: _____

CAUTION Harmful if swallowed,
inhaled or absorbed through the skin.
Avoid breathing vapors. Avoid
contact with eyes, skin or clothing.

**STATEMENT OF PRACTICAL
TREATMENT** In case of contact
immediately flush eyes or skin with
plenty of water. Get medical attention if
irritation persists.

45631-RI

EPA Reg. No. ~~68889~~
EPA Est. No. 035-347-CA-001
Manufactured by:
Alcide Corporation
Redmond, WA 98072
Distributed by:
Substrate Technologies Inc.
Fairfield, CT 06432

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 claims 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.

* Kills: Influenza Virus Type A2 (Hong Kong); Herpes Simplex Virus Types 1 & 2;
Poliovirus Type 1; Coxsackievirus; Adenovirus Type 2; Echovirus Type 2;
Vaccinia Virus and Vesicular Stomatitis Virus (VSV).

+ Currently, there is no established test for hepatitis viruses

Active Ingredients	Sodium Chloride	00.51%
Inert Ingredients		99.49%
Total		100.00%

Keep Out Of Reach Of Children

CAUTION: See Side Panel For

Additional Precautionary Statements

NET WEIGHT: 22 Fluid Ounces (628.5 ml)

SD - 3

DISINFECTANT

For Hard Non-Porous Surfaces

Prediluted - Ready to Use

For Use Only with SD-3 Trigger Sprayer Handle

SD-3 KILLS BACTERIA, FUNGI & VIRUSES*+ ON ENVIRONMENTAL SURFACES

SD-3 is effective against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, *Mycobacterium tuberculosis*,
in organic soil in 3 minutes.

Kills HUMAN IMMUNODEFICIENCY VIRUS Type 1 (HIV-1) in 30 seconds
on pre-cleaned environmental surfaces/objects previously soiled with
blood/body fluids in healthcare or other settings.

SD-3 Surface Disinfectant is recommended for use in dental offices, medical facilities, hospitals, schools, and for industrial and institutional applications to eliminate human health-related microorganisms on hard, non-porous environmental surfaces.

DIRECTIONS FOR USE

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

APPLICATIONS

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

PREPARATION

The solutions in each bottle of the twin-pack are prediluted and ready for dispensing through the Trigger Spray Handle. Remove the screw caps on each bottle and place the Trigger Spray Handle on the bottle openings with the locking levers on the Handle in the "OFF" position as indicated on the shoulder of each bottle. The Handle can only be seated on the twin-pack in one way. When the Handle is completely seated, move the lock-levers to the "ON" position as shown on the shoulder of each bottle. Proceed to dispense as instructed.

SPRAY ACTION

The ideal spray action is to pull or squeeze the handle fully and then to release it or let it go completely so that it returns freely to the original or open position. A short pumping action should not be used. Spraying is the best method of application. However, the solution may be wiped on by any convenient means (cloth, sponge etc.) The surface should be thoroughly wet with solution for the required 3 minute contact time and then dried with a cloth or paper towel. Each week wipe the sprayed surfaces with a damp cloth to remove any residue build-up.

KILL SPECTRUM

SD-3 solution will inactivate bacteria, viruses, pathogenic fungi and *M. tuberculosis* in 3 minutes at 20°C. Moderate amounts of organic load, such as soil, will not lower the efficacy of SD-3 solution. To ensure best results, surfaces should be rinsed free of heavy soil and gross debris. Hollow objects must be flushed and filled with disinfectant. User judgment and standard practice may require rinsing with sterile water prior to drying.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (AIDS) VIRUS ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.
Personal Protection: Wear protective barriers such as disposable latex gloves, gowns, masks, and/or eye coverings when handling items soiled with blood and body fluids.
Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of SD-3 Disinfectant.

Contact Time: SD-3 Disinfectant kills HIV-1 (AIDS) Virus at a 30 second contact time. This contact time is not sufficient to control other pathogens. See main panel on label for specifics.
Disposal Of Infectious Material: Blood, other body fluids, and contaminated cleaning materials should be autoclaved and disposed of according to local regulations for infectious waste disposal.

NOTE: SD-3 disinfectant may be used on formica, stainless steel, enamel painted, aluminum, treated wood, plastic, glass and ceramic surfaces including floors, walls, and bathroom fixtures. After 3 minutes contact time the surface should be dried with a cloth to avoid possible oxidation of metal surfaces. Do not use on copper, brass or bronze. Do not apply to surfaces with residues from bleach, strong acids or other chemicals, without first rinsing the surface thoroughly with water.

STORAGE AND DISPOSAL. Store unused bottle sets in a cool, dark dry place in original containers. Keep containers upright. Wash empty containers thoroughly with water and offer for recycling or discard in trash. Do not reuse containers. Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.



SD-3 ACTIVATOR



SD-3 BASE

W
P
W