

1043-90 17 31

U.S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (WH-567) WASHINGTON, D.C. 20460	EPA REGISTRATION NO. 1043-90	DATE OF ISSUANCE 10 FEB 1986
	TERM OF ISSUANCE	
NOTICE OF PESTICIDE: <input checked="" type="checkbox"/> REGISTRATION <input type="checkbox"/> REREGISTRATION (Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)	NAME OF PESTICIDE PRODUCT	

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

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 [Faint illegible text]

NOTE: Changes in labeling formula 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 U.S. 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.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this 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.

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[Faint illegible text]

[Faint illegible text]

- a. Add the phrase "EPA Registration No. 1043-90".
- b. Add the phrase "certified limit". State that you are not declaring pest at the active ingredient that the lower certified limit.
- c. For our records submit the results of one year storage and stability data.
- d. Delete from pesticide disposal instructions "or burial away from water supplies", and delete from container disposal instructions "or bury", the last part of the instructions.

ATTACHMENT IS APPLICABLE

SIGNATURE OF APPROVING OFFICIAL	DATE
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e. Efficacy Supported by Data

The bactericidal, fungicidal, and virucidal data, that were previously submitted and accepted for the product, Coverage 256, EPA Reg. No. 1043-82, may be utilized to support the efficacy of the subject product when used according to label directions.

The effectiveness of the subject product formulation is indicated by the confirmatory data submitted.

f. Food Additive Regulation

The submitted data, developed at a 1:768 dilution of the product in 500 ppm hard water (as CaCO_3) by the AOAC Germicidal and Detergents Sanitizers Test, indicate that the product is effective as a sanitizing rinse for food contact surface. However, the establishment of a food additive regulation by the Food and Drug Administration is required for the acceptance of these data to support sanitizing claims. The recommendation for a potable water rinse after the sanitizing treatment is not an alternative for this requirement.

g. Labeling

In lieu of a food additive regulation for the subject formulation, the efficacy claims and pattern of use for sanitizing food contact surfaces are not acceptable and must be deleted from the label.

The pattern of use for disinfecting food contact surfaces, followed by a potable water rinse, is being accepted. However, since this product formulation and the disinfecting pattern of use are not cleared for food contact surfaces, evidence to show the level of chemical residual on the treated surface may be required in the future.

On the right panel, "all" in the phrase "all washable hard non-porous surfaces" must be deleted since it is too inclusive and exclusive of none.

The phrase "infectious disease control" must be revised to read "infectious contamination control" to reflect the intended use of the product.

The claim "rapid" in reference to the product's cleaning and disinfecting capabilities is not acceptable and must be deleted since the term implies a shorter period than the 10 minutes recommended.

3. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-71 Enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e) our release for shipment of the product constitutes acceptance of these conditions.

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

Sincerely yours,

John H. Lee
Product Manager (31)
Disinfectants Branch
Registration Division (TS-767C)

Enclosure

FRONT PANEL

(VESTAL LOGO)

COVERAGE NPD
ONE-STEP GERMICIDAL DETERGENT

Germicide * Fungicide * Virucide * Detergent * Sanitizer * Deodorizer * Concentrate

E.P.A. REG. NO. 1043-xx

Active Ingredients:

Octyl decyl dimethyl ammonium chloride	4.60%
Diocetyl dimethyl ammonium chloride	2.30%
Didecyl dimethyl ammonium chloride	2.30%
Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆) dimethyl benzyl ammonium chloride	6.14%
Inert Ingredients:	84.66%

FOR AGRICULTURAL, INDUSTRIAL AND INSTITUTIONAL USE

Only for Sale To, Use and Storage by Service Personnel

DANGER: KEEP OUT OF REACH OF CHILDREN

STATEMENT OF PRACTICAL TREATMENT

In case of eye contact, flush with water for 15 minutes. Get prompt medical attention. For skin contact, flush with water. See side panel for additional precautionary statements.

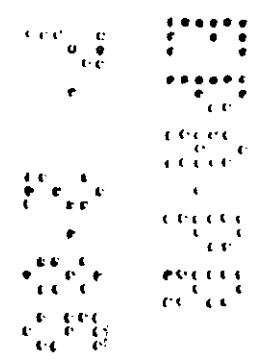
ACCEPTED
with COMMENTS
by EPA Letter Dated:

Contents: One U.S. Gallon (3.78 Liters)

FEB 13 1986

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

1043-90



Precautionary Statements

HAZARD TO HUMANS AND DOMESTIC ANIMALS: Concentrate corrosive. Causes eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed. Concentrate may be fatal if absorbed through the skin.

STATEMENT OF PRACTICAL TREATMENT: In case of eye contact, immediately flush eyes with water for 15 minutes and get prompt medical attention. For skin contact, flush thoroughly with water. Remove and wash contaminated clothing before reuse. If swallowed, drink large quantity of milk, egg white, gelatin solution, or water, avoid alcohol. Do not induce vomiting. Call 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.

DIRECTIONS FOR USE

1043-90
FEB 10 1986

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

Registered under EPA Reg. No.

CLEANING AND DISINFECTING: Add one-half ounce (15cc) to each measured gallon of water used. Always add this product to premeasured water. Gently mix for a uniform solution. Apply solution with a cloth, sponge, mop or brush using normal cleaning methods. Thoroughly wet all surfaces to be cleaned, then remove excess solution with a wrung-out applicator. Treated surfaces should remain wet for ten minutes. Remove gross filth mechanically by sweeping before cleaning begins. Discard solution when dirty and replace with a fresh solution. This is a complete product. Do not add other chemicals. Use only as directed.

ANIMAL HUSBANDRY, ANIMAL RESEARCH, POULTRY FACILITY CLEANING AND DISINFECTING: Remove or cover all food, feedstuffs, packaging materials and livestock. Remove all litter, manure and other debris from floors and walls; scrape if necessary. Empty all troughs, racks, feeders and waterers. Saturate all surfaces with a 1:256 solution (1/2 ounce per gallon prepared as directed above). Scrub to loosen adhering soils. Allow to soak for 10 minutes, then pick up excess with a wrung-out applicator. Flush feeders and waterers with potable water after disinfecting. Drain all surfaces, ventilate buildings and allow to air-dry before use or rehousing animals.

CLEANING AND DISINFECTING FOOD PREPARATION AND PROCESSING FACILITIES AND EQUIPMENT: Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the use-solution (1/2 ounce per gallon prepared as directed above). Scrub to loosen all soils. Allow to soak for 10 minutes. Thoroughly rinse all wetted and cleaned surfaces with potable water.

SANITIZING: Thoroughly clean all surfaces using this germicidal detergent, a detergent or soap solution. Rinse with potable water. Apply a use-solution (1/2 ounce per gallon prepared as directed above) to thoroughly wet all surfaces. Allow to soak for 30 seconds. Drain all surfaces and allow to air-dry before use. Treated food-contact surfaces must be rinsed with potable water after 30-second sanitizing treatment.

STORAGE AND DISPOSAL

PROHIBITIONS: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

PESTICIDE DISPOSAL: This germicide, its solutions or rinsings from empty containers, should be disposed of in a toilet or service sink served by a sanitary sewer, in a landfill approved for pesticides or buried away from water supplies.

CONTAINER DISPOSAL: Triple rinse and deposit in a waste container for incineration or in a landfill approved for pesticide containers, or bury.

GENERAL: Consult, Federal, State, or Local disposal authorities for approved alternative procedures such as limited open burning. If frozen, thaw and remix before use.

This product is a research-developed hard water effective, phosphate-free concentrated germicidal detergent system designed to simultaneously clean, disinfect and deodorize in the presence of 5% organic soil (serum) when diluted with 400 ppm hard water. It is intended for use on all washable hard non-porous environmental surfaces such as floors, walls, counters, tools, carts, and other equipment in food processing, preparation and service facilities, in animal husbandry, poultry and feed processing facilities, veterinary clinics, animal research facilities, and in other indoor areas where infectious disease control is a necessity. Use the use-solution for the rapid cleaning and disinfection of metal surfaces such as stainless or galvanized steel and chrome, porcelain, plastics, glass, tile, washable painted or varnished surfaces, concrete, as well as resilient vinyl, asphalt, linoleum, rubber, terrazzo or other combination-type floors. It may also be used as a sanitizer on pre-cleaned and rinsed hard non-porous environmental surfaces.

Germicide: Passes A.O.A.C. Germicidal Use-Dilution Method (*S. aureus*, *S. Choleraesuis*, *Ps. aeruginosa*) when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (1/2 ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

It has also been shown in the A.O.A.C. Use-Dilution Test, when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 solution (1/2 ounce per 1 gallon of water) in the presence of 5% organic soil (serum), 10 minutes at 20°C to inactivate:

Acinetobacter calcoaceticus, ATCC 19606
Candida albicans, Clinical Isolate
Candida parapsilosis, Clinical Isolate
Citrobacter freundii, ATCC 8090
Enterobacter aerogenes, ATCC 13048
Enterobacter cloacae, ATCC 23355
Escherichia coli, ATCC 25922
Klebsiella pneumoniae, ATCC 13883
Proteus vulgaris, ATCC 13315
Pseudomonas aeruginosa, ATCC 27853

Salmonella typhimurium, ATCC 14028
Serratia marcescens, ATCC 8100
Shigella flexneri, ATCC 12022
Shigella sonnei, ATCC 25931
Staphylococcus aureus, ATCC 25923
Staphylococcus aureus (MRSA),
Multiply (Methicillin)-Resistant
Clinical Isolate
Staphylococcus epidermidis, ATCC 12228
Streptococcus faecalis, ATCC 19433
Streptococcus pyogenes, ATCC 19615

Sanitizer: Passes A.O.A.C. Germicidal and Detergent Sanitizer Test (*S. aureus*, *E. coli*) when diluted with 500 ppm A.O.A.C. hard water, 30 seconds at 25°C.

Fungicide: Passes A.O.A.C. Fungicidal Test (*T. mentagrophytes*) when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (1/2 ounce per 1 gallon) solution, in the presence of 5% added organic soil (serum), 10 minutes at 20°C.

*Virucide: Passes Virucidal Assay (EPA Proposed Method) [*Influenza A₂* (Japan), *Herpes simplex* Types 1 and 2, *Vaccinia*] when diluted with 400 ppm hard water to make a 1:256 (1/2 ounce per gallon) solution, in the presence of organic soil (serum), 10 minutes at 20°C on hard non-porous inanimate environmental surfaces.

Odor Control: Eliminates most odors by killing odor-causing bacteria and simultaneously chemically neutralizing their odors. Cleans unpleasant-smelling soils.

Vestal Laboratories, Inc. **ACCEPTED**
A Subsidiary of Chemagro Corp. **COMMENTS**
St. Louis, MO 63110 in EPA Letter Dated: EPA Est. No. 1043-MO-1

Product No.
Label No.

FEB 10 1986

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Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
1043-90