

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 18 1994

Ann Vu
Calgon Vestal Laboratories
Division of Calgon Corporation
PO Box 147
St. Louis, MO 63166

Subject: 1 Stroke Environ
EPA Registration No. 1043-26
Your Amendment Dated March 31, 1993

Dear Ms. Vu:

This is in response to your labeling amendment for additional bactericidal efficacy claims.

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable subject to the comments listed below. A stamped copy is enclosed for your records. Five copies of the finished labeling must be submitted before the product is released for shipment bearing the amended labeling.

1. In the Container Disposal instructions under the Storage and Disposal heading, replace the word "burial" with "disposal".

2. Three lines below the Directions for Use heading, where it says "...washable precleaned, hard environmental surfaces...", insert the word "nonporous".

3. In the directions for use, expand the "Mushroom Farm Use" heading to specify cleaning and sanitizing of non-food contact surfaces. (A disinfection claim would not be appropriate.)

4. At the bottom of the last page of the draft labeling, where it says "...washable hard surfaces...", insert the word "nonporous".

CONCURRENCES

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

2 y 5

Your submitted efficacy studies (MRID Numbers 427230-01, -02, -03, -04, and -05) are acceptable in support of the revised labeling.

If you have any questions about these comments, please call Wallace Powell at 703-305-6938.

Sincerely,



Ruth G. Douglas
Product Manager 32
Antimicrobial Program Branch
Registration Division (7505C)

)
Enclosure

)

395

1STROKE ENVIRON[®]

U.S. PATENT NO. 3,538,217

EPA REGISTRATION NO. 1043-26

Germicide • Fungicide • Pseudomonacide
Tuberculocide • Virucide* • Deodorant

ACTIVE INGREDIENTS:

sodium o-phenylphenate	11.3%
sodium o-benzyl-p-chlorophenate	9.4%
sodium p-tertiary-amylphenate ..	2.3%

INERT INGREDIENTS 77.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

Statement of Practical Treatment

FIRST AID: In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse. If swallowed, do not induce vomiting. Drink promptly a large quantity of water. Avoid alcohol. 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.

NET CONTENTS: 1 U.S. GALLON (3.78 Liters)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

BEST AVAILABLE COPY

AUG 18 1994

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

1043-26

495

PRECAUTIONARY STATEMENTS
Hazard to Humans and Domestic Animals:

DANGER

Read carefully the following statement which applies to the contents of this container.

Corrosive to tissues. Causes eye and skin damage. Harmful or fatal if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles and rubber gloves when handling. Avoid contamination of food.

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 or in a land fill approved for pesticides.

Container Disposal: Triple rinse and deposit in a waste container for incineration or burial in a landfill approved for pesticide containers.

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

DIRECTIONS FOR USE

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

For use on all washable pre-cleaned, hard environmental surfaces including tuberculous areas, use 1:256 ($\frac{1}{2}$ ounce/gallon of water) solution. For accurate solution preparation, use Calgon Vestal's 1-Stroke Dispenser (one stroke delivers $\frac{1}{2}$ oz. of product). This is a complete product. Do not add other chemicals. Use only as directed.

CLEANING AND DISINFECTING ANIMAL AND POULTRY FACILITIES - Do not use in milking stalls, milking parlors, or milk houses. Cover or remove all food, feedstuffs, packaging material, and animals. Remove all dirt, litter and debris from surfaces to be disinfected. Thoroughly clean all surfaces with soap or detergent and rinse with water. Apply use solution with a sponge, mop or coarse spray to thoroughly wet all surfaces. Allow the surface to remain wet for 10 minutes and remove excess solution with a wrung-out applicator. Discard solutions when they become soiled and replace with a fresh solution of this product. Wash all feeders and waterers with a detergent and rinse with potable water before reuse. Ventilate buildings, coops, and other closed spaces. Allow disinfected areas to dry before rehousing livestock. Always remove gross filth and heavy soil before application of the solutions of this product.

CLEANING AND DISINFECTING FOOD CONTACT SURFACES, TOOLS AND EQUIPMENT - Cover or remove all food and packaging materials. Thoroughly clean surfaces to be disinfected before application of the solutions of this product. Apply use solution to the surface being disinfected with a sponge, mop or cloth and allow to remain wet for 10 minutes. Discard soiled solutions and replace with fresh use solutions. Rinse all surfaces with a potable water rinse after disinfection, and allow to air dry before reuse.

FOGGING AS AN ADJUNCT TO REGULAR CLEANING AND DISINFECTING - This product may be used in fogging (wet misting) as an adjunct either preceding or following regular cleaning and disinfecting procedures in Poultry operations, Hatcheries, Swine operations, Animal Care facilities, Animal Research facilities, Livestock operations and Veterinary facilities, Zoos, and Kennels. Use a 1:256 dilution ($\frac{1}{2}$ ounce per gallon of water). Fog the desired area at 32 to 64 ounces of use dilution per 1000 cubic feet using equipment with an automatic timer. Do not remain in treated areas; allow at least two hours after fogging is complete before reentering fogged area. Before fogging remove or carefully protect all food and packaging materials with waterproof coverings. Treated food contact surfaces must be thoroughly scrubbed with 1-Stroke Environ at a 1:256 dilution and rinsed with potable water before reuse.

MUSHROOM FARM USE - A normal use-solution ($\frac{1}{2}$ ounce per gallon of water) may be used between crops on surfaces that do not come in contact with the crop. Use on tanks, air conditioners, air ducts, fans, and breezeways, compost wharf, concreted surfaces, inside and outside walls of mushroom houses, lofts, floors, spawning machines, tampers, casing rings, storage sheds and track alleys before spawning. Thoroughly clean all surfaces with soap or detergent and rinse with water. Then apply use-solution with cloth, sponge, mop or coarse spray to thoroughly wet all surfaces; allow to remain wet for 10 minutes. Apply ONLY to surfaces that do not come in contact with the crop. Do not apply to the crop, compost or casings.

ACCEPTED
with COMMENTS
EPA Letter Dated:

AUG 18 1994

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

1043-26

BEST AVAILABLE COPY

1-Stroke Environ®

5 3 5
7

1-Stroke Environ is a detergent based germicide developed especially to control cross contamination of treated surfaces in the agricultural and food industries, and by the veterinary profession. It is intended for use on precleaned hard non-porous surfaces including floors, walls, counters, equipment in food processing areas, feed racks, troughs, and automatic feeders. It may be used in food processing, preparation and service facilities, in animal and avian husbandry, poultry and feed processing facilities, veterinary clinics, animal research facilities and mushroom farms.

When used as directed, this product is effective against pathogenic bacteria such as *S. aureus*, *S. choleraesuis*, *Ps. aeruginosa*, *M. tuberculosis* and fungi (*T. mentagrophytes*) when tested at 1:256 by official A.O.A.C. methods in either hard (400 ppm) or soft water; and *viruses (Influenza A₂, Herpes simplex, Type 2 Adenovirus, Vaccinia, Newcastle's disease, Infectious laryngotracheitis, Infectious bronchitis, Marek's Agent (JM-V), Hot Cholera) on inanimate environmental surfaces in 10 minutes at 20° C.

When tested according to A.O.A.C. Use-Dilution Testing, 1-Stroke Environ was shown to be effective against the following when diluted 1:256 (1/2 oz. per gallon) in 400 ppm A.O.A.C. hard water and 5% organic soil (serum) in 10 minutes at 20° C.

Aeromonas hydrophila, ATCC 7965
Bordetella avium, ATCC 35086
Corynebacterium sepeidonicum,
ATCC 9850
Klebsiella pneumoniae, ATCC 23357

Mycoplasma gallisepticum, ATCC 19610
Pasteurella multocida, ATCC 29977
Ps. aeruginosa, ATCC 13388
Salmonella enteritidis, ATCC 13076
Salmonella serovar pullorum, ATCC 19945

1-Stroke Environ was shown to be effective against *Escherichia coli* ATCC 11229, *Listeria monocytogenes* ATCC 15313 and *Campylobacter jejuni* ATCC 29429 when tested at a 1:256 dilution by official A.O.A.C. methods in hard (400 ppm) water on inanimate environmental surfaces in 10 minutes at 20° C.

1-Stroke Environ has been proven effective against the following viruses*; pseudorabies virus, porcine rotavirus and Transmissible gastroenteritis virus by the EPA proposed virucidal assay method when diluted 1:256 with 400 ppm hard water in 10 minutes at 20° C on inanimate environmental surfaces.

GERMICIDAL QUALIFICATION (A.O.A.C. Use Dilution Confirmation), 10 minutes at 20° C, when diluted 1:256 in (400 ppm CaCO₃). Remove heavy soil and preclean surface before application of product.

Fungicidal Test (A.O.A.C.T. mentagrophytes), 10 minutes at 20° C when diluted 1:256 in (400 ppm CaCO₃) A.O.A.C. hard water.

GERMICIDAL, PSEUDOMONACIDAL, TUBERCULOCIDAL AND FUNGICIDAL BY OFFICIAL A.O.A.C. QUALIFICATION IN SOFT OR HARD WATER (A.O.A.C. 400 ppm as CaCO₃) IN TEN MINUTES AT 20° C.

This product is recommended for use on washable hard surfaces such as counters, equipment, resilient tile flooring, terrazzo and painted or varnished surfaces.

1-Stroke Environ helps in the control of cross contamination and odors of bacterial origin.

Primary skin and eye irritation scores of 1:256 dilutions-0 when tested according to 16 CFR 1500.41 and 1500.42.



DIVISION OF CALGON CORPORATION
SUBSIDIARY OF MERCK & CO., INC.
St. Louis, Missouri 63133

5397-06A(990)

PRODUCT MADE IN U.S.A.

ACCEPTED
with COMMENTS
in EPA Letter Date:
AUG 10 1994
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No
104726