

Reg # 1043-91

PM-32

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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: LpHag
EPA Registration No. 1043-91
Your Amendment Dated April 21, 1993

Dear Ms. Vu:

This is in response to your labeling amendment for additional bactericidal and virucidal 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 one comment: submit five copies of the finished labeling before you release the product for shipment bearing the amended labeling. A stamped copy is enclosed for your records.

Your submitted efficacy studies (MRID Numbers 427482-01, -02, -03, and -04) 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

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

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LpH[®] ag

ONE-STEP GERMICIDAL DETERGENT

Germicide • Fungicide • Virucide*
Tuberculocide • Deodorizer • Cleaner • Detergent

*When diluted with soft or hard water
(400ppm CaCO₃) even in the presence of organic soil
(5% blood serum)*

EPA REG. NO. 1043-91

FOR AGRICULTURAL, INDUSTRIAL AND INSTITUTIONAL USE ONLY

Active Ingredients:

o-phenylphenol	7.3%
p-tertiary amyphenol	7.4%
Inert Ingredients	85.3%

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 immediately. See side panel for additional precautionary statements.

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

AUG 18 1994

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

1043-91

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LEFT PANEL

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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.

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 a large quantity of milk, egg whites, 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

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

CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES: To make solution, add 1/2 fl. oz. (15 cc) to each premeasured gallon of water and gently mix until solution is uniform. **NOTE:** Always add this product (concentrate) to premeasured water. Apply solution with a cloth, sponge, coarse spray, mop or brush using normal cleaning methods. Then remove excess solution with a wrung-out applicator. Allow treated surfaces to soak for 10 minutes. As solution becomes dirty, discard and replace with a fresh one. Before cleaning begins, always sweep or dust mop area to be cleaned thoroughly, removing any gross filth. This is a complete product. Do not add other chemicals. If frozen, thaw and remix before use. Use only as directed.

ANIMAL HUSBANDRY, ANIMAL RESEARCH, POULTRY HOUSE FACILITY CLEANING AND DISINFECTION: Do not use in milking stalls, milking parlors or milk houses. 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, feed and water appliances. 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.

FOGGING AS AN ADJUNCT TO REGULAR CLEANING AND DISINFECTING: This product may be used in fogging (wet misting) as an adjunct either proceeding or following regular cleaning and disinfecting procedures in research and manufacturing facilities, in poultry operations, hatcheries, swine operations, animal care facilities, animal research facilities, livestock operations, veterinary facilities, zoos and kennels. Use a 1:256 dilution (1/2 ounce per gallon of water). Remove all animals and feed from areas to be fogged. Remove all litter and manure from surfaces or areas traversed by animals. Empty all trough, racks and other feeding and watering appliances. Thoroughly clean all surfaces. 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 cover any food or packaging material with waterproof coverings. Treated surfaces must be thoroughly scrubbed with LpH_{AG} at a 1:256 dilution and rinsed with potable water before reuse. Do not rehouse livestock or employ equipment until treatment has dried.

KILLS HIV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1)(associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

External Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of a 1:256 use-solution (1/2 ounce per gallon). Prepare and apply solution as directed in paragraph above. **Contact Time.** While the HIV 1 virus is inactivated in 1 minute, use a 10-minute contact time for disinfection of all organisms on this label. **Infectious Materials Disposal:** Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious disposal.

CLEANING AND DISINFECTING FOOD PREPARATION, PROCESSING FACILITIES AND EQUIPMENTS: 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, then pick up excess solution with a wrung-out applicator. Thoroughly rinse and wetted and cleaned food contact surfaces with potable water.

DISINFECTION AGAINST CANINE PARVOVIRUS AND INFECTIOUS BURSAL DISEASE VIRUS: To make solution, add 2 fl. oz. (60 cc) to each premeasured gallon of water and gently mix until solution is uniform. Apply the use-solution as specified above.

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 landfill approved for pesticides.

GENERAL: Consult Federal, State, or Local disposal authorities.



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

ACCEPTED
with COMMENTS
in EPA Letter Dated
AUG 18 1994
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended for the pesticide
registered under EPA Reg. No.
104291

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RIGHT PANEL

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This state-of-the-art non-alkaline phenolic germicidal detergent is a multi-purpose product. Scientifically developed to be both hard water and serum effective in a concentrated system, it produces a use solution designed to clean, disinfect and deodorize in a simple one-step process. In addition, the non-alkaline formula removes soap scum and hard water scale which can harbor bacteria. Use this product on 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 and avian husbandry, poultry and feed processing facilities, veterinary clinics, animal research facilities and in other indoor areas where anti-bacterial control measures are necessary.

Use for one-step cleaning, disinfecting and deodorizing of 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 and other combination type floors.

GERMICIDAL: The 1:256 (1/2 ounce per gallon) solution passes the A.O.A.C. Germicidal Use-Dilution Test (*S. aureus*, *S. choleraesuis*, *Ps. aeruginosa*) when diluted with 400 ppm A.O.A.C. hard water, in the presence of 5% organic soil (serum), 10 minutes at 20° C.

- Acinetobacter calcoaceticus*, ATCC 19606
- Aeromonas hydrophila*, ATCC 7965
- Bordetella avium*, ATCC 35086
- Campylobacter jejuni*, ATCC 29428
- 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
- Listeria monocytogenes*, ATCC 15313
- Mycoplasma gallisepticum*, ATCC 19610
- Pasteurella multocida*, ATCC 29977
- Proteus mirabilis*, Clinical Isolate
- Proteus vulgaris*, ATCC 13315

- Pseudomonas aeruginosa*, ATCC 27853
- Salmonella enteritidis*, ATCC 13076
- Salmonella sp. Serovar pullorum*, ATCC 19945
- Salmonella typhi*, ATCC 6539
- 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
- Streptococcus suis*, ATCC 43765

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

TUBERCULOCIDAL: The 1:256 (1/2 ounce per gallon) solution passes the A.O.A.C. Tuberculocidal Test (*Mycobacterium tuberculosis*, var. *bovis* [BCG]) when diluted with 400 ppm A.O.A.C. hard water, in the presence of 5% organic soil (serum), 10 minutes at 20° C.

***VIRUCIDAL:** The 1:256 (1/2 ounce per gallon) solution passes the Virucidal Assay (EPA Proposed Method) against (Influenza A, [Japan], Herpes simplex Type 2, Vaccinia, Avian Reovirus, Avian Influenza Virus, Adenovirus Type 2, Newcastle Disease, Pseudorabies, Infectious Bronchitis, Porcine rotavirus, Infectious laryngotracheitis, Transmissible gastroenteritis, Canine distemper, and Marek's Disease) on hard inanimate surfaces when diluted with 400 ppm A.O.A.C. HARD WATER, IN THE PRESENCE OF 5% organic soil (serum), 10 minutes at 20°-25° C.

A 1.64 (2 fl. oz. per gallon) solution passes the Virucidal Assay (EPA Proposed Method) against Canine Parvovirus and Infectious Bursal Disease Virus on hard inanimate surfaces when diluted with 400 ppm A.O.A.C. hard water, in the presence of 5% organic soil (serum), 10 minutes at 20°-25° C.

+ When tested by an EPA-approved Dilution Method, the HIV-1 (AIDS) virus, with added 5% organic soil (serum), was completely inactivated by a 1:256 (1/2 ounce per gallon) solution in 400 ppm A.O.A.C. hard water in 60 seconds at 20° C. Although efficacy at a 1-minute contact time has been shown to be adequate against HIV-1, this time would not be sufficient for other organisms. Use a 10-minute contact time for disinfection against all of the organisms claimed.

ODOR CONTROL: It eliminates many odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors.

6341-06D(493)

EPA Est. No. 1043-MO-1

ACCEPTED
with COMMENTS
in EPA Letter Dated:

4/16 18 1994

Under the Federal Insecticide,
Fungicide and Rodenticide Act as
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