

FEB 8 1989

Calgon Vestal Laboratories  
Division of Calgon Corporation  
Subsidiary of Merck and Company, Inc.  
5035 Manchester Avenue  
St. Louis, MO 63110

Attention: E. Nouss

Gentlemen:

Subject: LPH ag One-Step Germicidal Detergent  
EPA Registration No. 1043-91  
Your Application Dated March 8, 1988  
EPA Received Date March 15, 1988

The submitted data meet the requirement to support effectiveness of the product as a virucide against HIV-1 (AIDS virus) on hard, nonporous surfaces in the presence of a moderate amount of organic soil (5% blood serum) when used at a 1/256 dilution in 400 parts per million CaCO<sub>3</sub> hard water for a contact time of 1 minute and/or 2 minutes at room temperature (20 to 25 °C).

The amendment referred to above submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, is accepted provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.
  - a. The contact times of 1 or 2 minutes employed for efficacy testing against HIV-1 does not correlate with the contact time of 10 minutes supported in previously accepted efficacy data for disinfection and the last accepted labeling for this product. Therefore, if a claim for shorter contact time is made for HIV-1, a statement similar to the following would be required:

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

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CONCURRENCES

SYMBOL	15767C						
SURNAME	J. Dutch						
DATE	2-6-89						

organisms. Use a 10-minute contact time for disinfection against all of the organisms claimed.

- b. The labeling requirements for antimicrobial pesticides used on hard surfaces against HIV-1 (AIDS virus) are indicated on the enclosure. It is important to note that featured statements/phrases, emphasized/enlarged lettering, special graphics, or any product name that employs the term "AIDS" is not acceptable, as indicated in item 2. Special instructions for this use pattern must be provided in the format indicated in item 4 of this enclosure.
  - c. The label reference to "HIV (AIDS) Virus" must be revised to read "HIV-1 (AIDS virus)."
2. Submit five (5) copies of the your final printed labeling before you release the product for shipment. 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.

Should you have any further questions, please contact Veronica Dutch at (703) 557-6938.

Sincerely yours,



Jeff Kempter  
Product Manager (32)  
Antimicrobial Program Branch  
Registration Division (TS-767C)

Enclosure

ACCEPTED  
with COMMENTS  
in EPA Letter Dated

FEB 06 1989

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

1043-41

**LpHag**

### ONE-STEP GERMICIDAL DETERGENT

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

When diluted with soft or hard water  
(400ppm CaCO<sub>3</sub>) even in the presence of organic soil (5%  
serum)

EPA REG NO 1043-91

FOR 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)**

The non-alkaline phenolic germicidal detergent is a state-of-the-art, concentrated scientifically developed product effective in hard or soft water even in the presence of organic soil (5% blood serum). The use-solution of this product when diluted 1/2 ounce per gallon of water is specifically formulated to clean, disinfect and deodorize in a simple one-step process. With its non-alkaline base, it will remove soap scum and hard water scale which can harbor bacteria. Use the product on all washable hard non-porous environmental surfaces such as floors, walls, counters, tables, carts, and other equipment in food processing preparation and service 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 steel and chrome porcelain, plastic, glass, tile, washable painted, & varnished surfaces, concrete, as well as resilient vinyl, asphalt, linoleum, rubber, terrazzo, and other combination type floors.

**GERMICIDAL:** When tested against *S. aureus*, *S. choleraesuis* and *Ph. aeruginosa*, it passes the A.O.A.C. Germicide Use-Dilution Test when diluted with 400 ppm A.O.A.C. hard water to make a 1.25% (1/2 ounce per 1 gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 20°C.

**BROAD SPECTRUM DATA:** The following additional organisms pass the A.O.A.C. Use-Dilution Test in 400 ppm A.O.A.C. hard water at a dilution of 1.25% in the presence of 5% organic soil (serum), 10 minutes at 20°C:

<i>Acetobacter calcoaceticus</i> ATCC 19620	<i>Salmonella typhi</i> ATCC 8639
<i>Candida albicans</i> Clinical isolate	<i>Salmonella typhimurium</i> ATCC 14029
<i>Candida parapsilosis</i> Clinical isolate	<i>Salmonella enteritidis</i> ATCC 8100
<i>Carexibacter freundii</i> ATCC 8080	<i>Shigella flexneri</i> ATCC 12022
<i>Enterobacter aerogenes</i> ATCC 13048	<i>Shigella sonnei</i> ATCC 25801
<i>Enterobacter cloacae</i> ATCC 23065	<i>Staphylococcus aureus</i> ATCC 25923
<i>Escherichia coli</i> ATCC 25822	<i>Staphylococcus aureus</i> (MRSA)
<i>Klebsiella pneumoniae</i> ATCC 13883	Multiply (Resistant)-Penicillin Clinical isolate
<i>Proteus mirabilis</i> Clinical isolate	<i>Staphylococcus epidermidis</i> ATCC 12228
<i>Proteus vulgaris</i> ATCC 13115	<i>Streptococcus faecalis</i> ATCC 19433
<i>Pseudomonas aeruginosa</i> ATCC 27853	<i>Streptococcus pyogenes</i> ATCC 19615

**FUNGICIDAL:** When tested against 17 microphytes, it passes the A.O.A.C. Fungicide Test when diluted with 400 ppm A.O.A.C. hard water to make a 1.25% (1/2 ounce per 1 gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 20°C.

**TUBERCULOCIDIC:** When tested against *Mycobacterium tuberculosis* var. *bovis*, BCG, it passes the A.O.A.C. Tuberculocidal Test when diluted with 400 ppm A.O.A.C. hard water to make a 1.25% (1/2 ounce per 1 gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 20°C.

**VIRUCIDAL:** When tested against Influenza A<sub>1</sub> (H1N1), Herpes simplex Type 2, Vaccinia, and Adenovirus Type 2, it passes the Viral Assay (I.P.A. Proposed Method) when diluted with 400 ppm A.O.A.C. hard water to make a 1.25% (1/2 ounce per 1 gallon) solution in the presence of 5% organic soil (serum), 10 minutes at 20°C.

When tested by an EPA approved Dilution Method, the HIV (AIDS) virus, with added 5% organic soil (serum), was completely inactivated by a 1.25% (1/2 ounce per 1 gallon) solution in 400 ppm A.O.A.C. hard water in 60 seconds at 20°C.

**ODOR CONTROL:** It eliminates many odors by killing odor-causing bacteria while simultaneously chemically neutralizing their odors and leaving a pleasant fragrance.

### 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 large quantities 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. (14cc) 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, mop or brush using normal cleaning methods. Then remove excess solution with a wring-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 dirt. This is a complete product. Do not add other chemicals. If frozen, thaw and remix before use. Use only as directed.

**CLEANING AND DISINFECTING FOOD PREPARATION, PROCESSING FACILITIES AND EQUIPMENT** Cover or remove all food and packaging materials. Remove all gross soil. Saturate all surfaces with the use-solution (1/2 ounce per gallon prepared as directed above). Scrub to loosen all soil. Allow to soak for 10 minutes, then pick up excess solution with a wring-out applicator. Thoroughly rinse all water and cleaned food contact surfaces with potable water.

### 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 mixings from empty containers, should be disposed of in a tank or service area served by a sanitary sewer, or in a landfill approved for pesticides.

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

**GENERAL** Consult Federal, State or Local disposal authorities for approved alternative procedures such as limited open burning.



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