

PM 32 1043-92 10/14

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Mr. George Mell
 Calgon Vestal Laboratories
 P. O. Box 147
 St. Louis, MO 63166

Dear Mr. Mell:

Subject: LpH_{aa}
 EPA Registration No. 1043-92
 Your Resubmission Dated July 25, 1995
 Letter Dated January 30, 1995

This is in response to your resubmission of revised labeling for new directions for use and new package size.

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 following comment.

1. Revise the ingestion statement to read:

"If swallowed, drink large amounts of water. Do not induce vomiting. Call a physician or poison control center immediately".

A stamped copy is enclosed for your records. Submit one copy of the final printed label.

If you have any questions, please call Marianne Clark at (703) 305-7879.

Sincerely yours,

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

CONCURRENCES

SYMBOL	R1						
SURNAME	J. S. [Signature]						
DATE	11/14/95						

Safe

LpH[®] se

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% serum)

EPA REG. NO. 1043-92
FOR INDUSTRIAL AND INSTITUTIONAL USE ONLY

Active Ingredients:

o-phenylphenol.7.3%
p-tertiary amylphenol.....7.4%
Inert Ingredients:.....85.3%

*CORRECTION to,
NO CHANGE SINCE LAST
APPROVED*

KEEP OUT OF REACH OF CHILDREN

DANGER:

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: 32 FL. OZ. (1 QUART) (946 ML)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 17 1995

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

1043-92

3044

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 one-half fl. oz (15 cc) to each pre-measured gallon of water and gently mix until solution is uniform. **NOTE:** Always add this product (concentrate) to pre-measured water. Apply solution with a cloth, sponge, mop or brush using normal cleaning methods. Allow treated surfaces to soak for 10 minutes. Then remove excess solution with a wrung-out applicator. 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 re-mix before use. Use only as directed.

INSTRUCTION
Directions for use with Twin-Neck Dispensing Bottle: To make one gallon (1:256) solution, loosen cap from dispensing chamber. Gently squeeze bottle to fill measuring chamber to the 1/2 fluid ounce line. Remove cap from dispensing chamber. Pour measured product (concentrate) from the chamber into one gallon (128 ounces) of pre-measured cold water and mix well. Apply as directed above.

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

Personal 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 (one-half ounce per 1 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 EQUIPMENT: Cover or remove all food and packaging materials. Remove all gross soils. Saturate all surfaces with the use-solution (one-half 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 all wetted 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 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.

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.

EPA Est. No. 1043-MO-1

Calgon Vestal Laboratories, Inc.
St. Louis, Missouri
with COMMENTS
in EPA Letter Dated:

NOV 17 1995

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 1043-92

Hyfey

This 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 (serum). The use-solution of this product when diluted one-half ounce per gallon of water is specifically formulated to clean, disinfect and deodorize in a slightly alkaline base, it will remove soap scum and hard water salts which can harbor bacteria. Use this product on all washable, hard, non-porous environments such as counters, tools, carts, and other equipment in food processing preparation and service facilities, veterinary clinics, animal research facilities and in other areas where high hygiene measures are necessary. This product is not for use in the neonatal (newborn) units in hospitals specifically isolettes and other infant contact surfaces.

Use for one-step cleaning, disinfecting and deodorizing of stainless or galvanized steel and chrome, porcelain, plastics, glass, tile, washable painted surfaces as well as resilient vinyl, asphalt, linoleum, rubber, terrazzo and other combination type floors.

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 blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily or otherwise enter normally sterile areas of the body.

GERMICIDAL: When tested against *S. aureus*, *S. choleraesuis* and *Ps. aeruginosa*, it passes the A.O.A.C. Germicidal Use-Dilution Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half 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 1:256 (one-half ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

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 mirabilis, Clinical Isolate
Proteus vulgaris, ATCC 13315
Pseudomonas aeruginosa, ATCC 27853
Salmonella typhi, ATCC 6539
Salmonella typhimurium, ATCC 14028
Serratia marcescens, ATCC 8100
Shigella flexneri, ATCC 12022
Shigella sonnei, ATCC 25931

Staphylococcus aureus
Staphylococcus aureus (Methicillin)-Resistant
Staphylococcus epidermidis
Streptococcus faecalis
Streptococcus pyogenes

FUNGICIDAL: When tested against *T. mentagrophytes*, it passes the A.O.A.C. Fungicidal Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

TUBERCULOCIDAL: When tested against *Mycobacterium tuberculosis var bovis*, BCG, it passes the A.C.A.C. Tuberculocidal Test when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half ounce per 1 gallon) solution, in the presence of 5% organic soil (serum), 10 minutes at 20°C.

***VIRUCIDAL:** When tested against Influenza A₂ (Japan), Herpes simplex Type 2, Vaccinia, and Adenovirus Type 2, it passes the Virucidal Assay (EPA Method 173) when diluted with 400 ppm A.O.A.C. hard water to make a 1:256 (one-half 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-1 (AIDS) virus, with added 5% organic soil (serum), was completely inactivated by a 1:256 (one-half ounce per 1 gallon) solution in 400 ppm A.O.A.C. hard water in 60 seconds at 20°C. Although efficacy at 1 minute contact time has been shown to be adequate against HIV-1, this time is not recommended 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 and leaving a pleasant fresh scent.