

22 APR 1994

Calgon Vestal Laboratories
 A Division of Calgon Corporation
 P.O. Box 147
 St. Louis, MO 63166-0147

Attn: Michael Ebers

Subject: LpHse
 EPA Registration No. 1043-92
 Your Correspondence of February 15, 1994 and
 Resubmission of March 25, 1994

The amendment request noted above, involving revised text on the product label for proposed use restrictions of the subject product has been reviewed. The following is a result of this review.

1. The proposal for restricting use of this product in neonatal areas in hospitals is supported by your correspondence of February 15, 1994 and is acceptable.

2. The proposed text incorporating the language of the joint EPA/FDA Memorandum of Understanding (MOU) is acceptable.

3. 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 printed labels must be submitted to Agency before releasing the product for shipment bearing the revised label text.

a. In the first paragraph of the Use Directions on page one of the draft label, add the statement: "Not to be used on food-contact surfaces."

b. Delete the last paragraph of the Use Directions on page one of the draft label which begins "Cleaning and Disinfecting Food ...". (Refer to EPA's letter of April 20, 1994 under this registration in regard to this use pattern for your formulation.)

CONCURRENCES

SYMBOL	75052						
SURNAME	Parsons						
DATE	22 APR 1994						

Jay4

If you should have any questions concerning this letter, you may call Robert Travaglini on (703) 305-6909.

Sincerely,



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

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CALGON VESTAL

314 535 1094

16:03

03/15/94

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. (15cc) 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 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.

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 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.

6456-06B(293)



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

EPA Est. No. 1043-MO-1

LpH
ONE-STEP GERMICIDE
DETERGENT

Germicide • Fungicide • Virus
• Deodorizer • Cleaner

When diluted with soft or hard water
in the presence of organic matter
EPA REG. NO. 1043-MO-1

FOR INDUSTRIAL AND INSTITUTIONAL USE

Active Ingredients:
o-phenylphenol
p-tertiary amylphenol
Inert Ingredients:

KEEP OUT OF REACH OF CHILDREN
DANGEROUS

STATEMENT OF PRACTICAL TREATMENT

In case of eye contact, flush 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. See side panel for additional statements.

NET CONTENTS: 1 GALLON (3.78 LITERS)

APPROVED
with COMMENTS
in EPA Letter Dated

22 APR 1994

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. 1043-9

1043-9

BEST AVAILABLE

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 soil (5% blood 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 simple one-step process. With its non-alkaline base, it will remove soap scum and hard water salts which can harbor bacteria. Use this product 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, veterinary clinics, animal research facilities and in other indoor areas where antibacterial control 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 or varnished surfaces, concrete, 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 human body, either into or in contact with the blood stream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier 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 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 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, ATCC 25923

Staphylococcus aureus (MRSA), Multiply (Methicillin)-Resistant Clinical Isolate

Staphylococcus epidermidis, ATCC 12228

Streptococcus faecalis, ATCC 19433

Streptococcus pyogenes, ATCC 19615

FUNGICIDAL: When tested against *T. montagrophytes*, 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.O.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 Proposed Method) 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 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 and leaving a pleasant fragrance.

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ACCEPTED
with COMMENTS
in EPA Letter Docket

22 APR 1994

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

1043-92