

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

PM 32

1043-91

1/5

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

JUN 21 1996

Attn: George Mell,
 Regulatory Specialist

Subject: LpH Master Product
 EPA Registration No. 1043-91
 Your Submission of June 12, 1996

This letter responds to the above dated reply to the Agency's letter of May 30, 1996 concerning your amendment of November 20, 1995. Enclosed with an updated product label, your letter requested action on labeling amendment and administrative issues from the November 20, 1995 submission which were not adequately addressed in the subsequent EPA response. This letter therefore supersedes the aforementioned May 30, 1996 correspondence. Please note the following.

1. The revised analytical method for determination of phenol content, submitted under MRID #438570-1, is acceptable.

2. The updated Confidential Statement of Formula (CSF) dated November 8, 1995 complies with PR Notice 91-2 and is acceptable.

3. The revised master product labeling is acceptable subject to the comments listed below. A stamped copy is enclosed for your records. Before releasing the product for shipment, submit one copy of the finished product labeling which incorporates these comments.

a. Revise the product name "LpH Master Products" to "LpH Master Product".

b. Change the product description: "One-Step Sterile Germicidal Detergent" to: "Sterile One-Step Germicidal Detergent".

c. The labeling hereby being accepted with this letter is considered master product labeling. Subsequent release of this labeling in alternative packaging or under additional brand names cannot contain any additional conditions or different use-directions.

SYMBOL	7505						
SURNAME	<i>Tracy</i>						
DATE	JUN 21 1996						

d. The active ingredient declarations in the Ingredient Statement (o-phenylphenol, p-tert amyphenol) are in accordance with the November 8, 1995 CSF, and PR Notice 91-2

4. The proposed additional brand name and additional packaging size are acceptable.

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

Sincerely,

R. J. Francis

Walter C. Francis
Acting Product Manager (32)
Antimicrobial Program Branch
Registration Division (7505C)

3/5

CENTER PANEL

(DRAFT)

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 21 1996

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

1043-91

LpH[®]

Master Product

ONE-STEP

STERILE

GERMICIDAL DETERGENT

Germicide • Fungicide • Virucide • Tuberculocide
• Deodorizer • Cleaner • DetergentWhen diluted with soft or hard water (400ppm CaCO₃) even
in the presence of organic soil (5% serum)

EPA REG. NO. 1043-91

EPA Est. No. 1043-MO-1

FOR AGRICULTURAL, INDUSTRIAL AND
INSTITUTIONAL USE ONLY

Active Ingredients:

o-phenylphenol.....	7.7%
p-tertiary amylphenol.....	7.6%
Inert Ingredients.....	84.7%

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: 5 U.S. Gallons (18.93Liters)

LEFT PANEL

4/5

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.

ENVIRONMENTAL HAZARD STATEMENT: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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, coarse spray, 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.

ANIMAL HUSBANDRY, ANIMAL RESEARCH, POULTRY, 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 (one-half 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 moving 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 preceding 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 (one-half 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 troughs, 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 Master Product at a 1:256 dilution and rinsed with potable water before reuse. Do not rehouse livestock or employ equipment until treatment has dried.

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.