

PM-32

Reg # 1043-91

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number
253227

Application for Pesticide - Section I

1. Company/Product Number 1043-91	2. EPA Product Manager Walter Francis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) LpH Master Product	PM# 32	
5. Name and Address of Applicant (Include ZIP Code) ConvaTec P. O. Box 147 St. Louis, MO 63166 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below _____

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

NOTIFICATION: Notification of addition of phrase to label inadvertently omitted from previous submission. "Sterile unless package is compromised".

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input checked="" type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
				<input checked="" type="checkbox"/> Other (Specify) foil pouches	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 oz./1,5,30 & 55 gallon		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input checked="" type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name George Mell	Title Regulatory Specialist	Telephone No. (Include Area Code) 314-533-2276
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Specialist	
4. Typed Name George Mell	5. Date 27 August 96	

8/27/96

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LpH[®]

Master Product STERILE 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. 1043-91
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%

NOTIFICATION
23 1996

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.

STERILE UNLESS PACKAGING IS COMPROMISED

NET CONTENTS: 1 fl. oz. (29.5 ml)

- 1 US Gallon (3.78 Liters)
- 5 US Gallons (18.93 Liters)
- 30 US Gallons (113.55 Liters)
- 55 US Gallons (208.18 Liters)



ConvaTec

Division of E.R. Squibb and Sons, Inc.
St. Louis, Mo 63110

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-PORUS 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, course 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 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 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.

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This state of the art, non-alkaline, phenolic germicidal detergent is a sterile, multi-purpose product specifically developed to be both hard water and serum effective in a concentrated system for use on hard, non-porous critical environment surfaces found in aseptic rooms and hoods; airlocks; gowning; barrier isolation; process equipment and piping systems. The use-solution is 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, pharmaceuticals, biotechnology, medical device and FDA regulated facilities, and in other areas where anti-bacterial control measures are necessary.

GERMICIDAL-The 1,256 (one half 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.

BROAD SPECTRUM DATA: The following organisms also 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 | Pseudomonas aeruginosa, ATCC 27853 |
| Aeromonas hydrophila, ATCC 7965 | Salmonella enteritidis, ATCC 13076 |
| Bordetella avium, ATCC 35086 | Salmonella sp. serovar pullorum, ATCC 19945 |
| Campylobacter jejuni, ATCC 29428 | Salmonella typhi, ATCC 6539 |
| Candida albicans, Clinical Isolate | Salmonella typhimurium, ATCC 14028 |
| Candida parapsilosis, Clinical Isolate | Serratia marcescens, ATCC 8100 |
| Citrobacter freundii, ATCC 8090 | Shigella flexneri, ATCC 12022 |
| Enterobacter aerogenes, ATCC 13048 | Shigella sonnei, ATCC 25931 |
| Enterobacter cloacae, ATCC 23355 | Staphylococcus aureus, ATCC 25923 |
| Escherichia coli, ATCC 25922 | Staphylococcus aureus, (MRSA),
Multiply (Methicillin)-Resistant
Clinical Isolate |
| Klebsiella pneumoniae, ATCC 13883 | Staphylococcus epidermidis, ATCC 12228 |
| Listeria monocytogenes, ATCC 15313 | Streptococcus faecalis, ATCC 19433 |
| Mycoplasma gallisepticum, ATCC 19610 | Streptococcus pyogenes, ATCC 19615 |
| Pasteurella multocida, ATCC 29977 | Streptococcus suis, ATCC 43765 |
| Proteus mirabilis, Clinical Isolate | |
| Proteus vulgaris, ATCC 13315 | |

FUNGICIDAL: The 1:256 (one half 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 (one half 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:** A 1:256 (one half ounce per gallon) solution passes the Virucidal Assay (EPA Proposed Method) against the following on hard inanimate surfaces when diluted with 400 ppm A.O.A.C. hard water, in the presence of 5% organic soil (serum), in 10 minutes at 20°-25°C. Influenza A₂ [Japan], Herpes Simplex Type 2, Vaccinia Virus, Adenovirus Type 2, Avian Reovirus, Avian Influenza Virus, Newcastle Disease, Canine Distemper, Pseudorabies, Infectious Bronchitis, Porcine Rotavirus, Infectious Laryngotracheitis, Transmissible Gastroenteritis, Marck's Disease.

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 (one half ounce per 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.