

675-43

01/19/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 19 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mary Pisculli
Regulatory & Registration Compliance Specialist
Reckitt Benckiser Inc.
Morris Corporate Center IV
399 Interpace Parkway
Parsippany, NJ 07054-0225

Subject: AMPHYL
EPA Registration No: 675-43
Application Date: October 21, 2011
Receipt Date: October 24, 2011

Dear Ms. Pisculli:

The following amendment(s), submitted in connection with registration of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Proposed Amendment

- Incorporate agency comments outlined in current approved master text label dated August 4, 2004
- Incorporate all previous agency approved notifications and non-notifications
- Correct typographical and grammatical errors
- Revise storage & disposal language in accordance to PR Notice 2007-4

Deficiencies

Revise your labeling to address the following:

1. Delete "(website)" on page one (1) you already provided your company email.
2. On page five (5) of the product label, you must include the applicable revise storage & disposal language in accordance to PR Notice 2007-4.
3. On page five (5) of the product label, you must include the applicable Environmental Hazards Statements: (If container size is less than 5 gallons, use the following Environmental hazards statement)

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic organisms. (If the container size is 5 gallons or larger, use the following Environmental hazards statement)

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries,

oceans or other waters unless in accordance with the requirements of National Pollutant Discharge Elimination Systems (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 of Regional Office of the EPA.

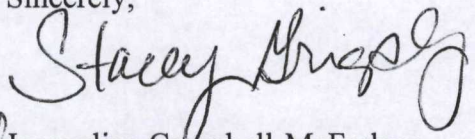
- 4. On page two (2) you may not include the phrase: "against pathogenic fungi" without qualifying those fungi. List specific fungi for which efficacy data has been submitted, reviewed and accepted by the Agency.
- 5. Delete "recommended" from the section listing the sites for this product, page two (2). The use of the term recommended is not in agreement with PR Notice 2000-5.
- 6. Delete "dental instruments and surgical instruments" on page (2). Both surfaces are not in agreement with PR Notice 2000-5.
- 7. Revise the language for hospital disinfection on page three (3) by deleting "should be" and "recommended" which are not in agreement with PR Notice 2000-5.

General Comments

Submit revised labeling for review.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Lorena Rivas by telephone at (703) 305-5027 or by e-mail at rivas.lorena@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



6/ Jacqueline Campbell-McFarlane
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

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<< FRONT PANEL >>

ACTIVE INGREDIENTS:

o-Phenylphenol	10.63%
o-Benzyl-p-chlorophenol	5.11%
OTHER INGREDIENTS:	<u>84.26%</u>
TOTAL:	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER: Corrosive. Causes eye damage and skin irritation.
See back (side) panel for additional precautionary statements and first aid.

NET CONTENTS: 128 FL. OZ. (1 GAL.) 3.78 L

<< FRONT / BACK PANEL >>

EPA Reg. No. 675-43
EPA Est. No. 09019-OH-001
09019-OH-002
066256-CN-001

(See bottom or side) (for Lot / Date code)

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JAN 19 2012
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 675-43

<< BACK PANEL >>


Questions? () (Comments?) (Call:) 1-800-677-9218
For ingredient (and other) information, (www.rbnainfo.com) (website)


Distributed by: Reckitt Benckiser, Parsippany, NJ 07054(-xxxx)
(Made in U.S.A.) (Made in Canada) © {year} RB

Contains no phosphates

This (bottle) (container) is made of 25% post-consumer recycled plastic.

NOTICE: This product contains a chemical known to the State of California to cause cancer.

Company graphic logo 

NSF certification symbol: 

<< BACK PANEL – Optional text >>

Recycle Symbol
Part of your infection control program
(This product) meets the requirements of the OSHA Bloodborne Pathogen Standard for Decontamination
(This product) meets AOAC Germicidal efficacy standards for hospital disinfectants

(This product) is part of a system of infection control products provided by Reckitt Benckiser. People respect the AMPHYL® Brand name for providing high quality and trusted surface disinfection and gain the added benefit of a clean, sanitary environment.

NOTE: Bracketed information is denoted as: << directive >>, { insert as noted }, (optional text), [required qualifier].
The term "this product" used throughout this document may be replaced with the marketed product brand name.
To use the term "germ*" the product must be efficacious against 2 of the 3 major classes of organisms.
The product label must identify the specific bacteria, virus, fungus & mold.
The term (x) is a placeholder that represents a number between 1 and 99.

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<< FRONT / BACK PANEL – CLAIMS – use as bullet point or in paragraph format >>

Disinfectant – Deodorant – Detergent
For Hospital Use
For use in Institutional (and Industrial) Facilities
Tuberculocidal* – Pseudomonacidal* – Germicidal* – Fungicidal* – Virucidal*
Dilute at (1:100) (1:200)

(This product) disinfects and deodorizes in one operation

- GERMICIDAL* – Staphylocidal (including Methicillin and Gentamicin Resistant Staphylococcus), Salmonellacidal, Pseudomonacidal, Tuberculocidal
- FUNGICIDAL* – against pathogenic fungi
- VIRUCIDAL* – against Influenza Virus Type A₂ [Hong Kong], Herpes Simplex Virus Type 1, Vaccinia Virus and Human Immunodeficiency Virus Type 1 [HIV-1 AIDS Virus]

* On hard, non-porous environmental surfaces

(This product) is recommended for use on hard, non-porous environmental surfaces in:

- Dental Offices
- Doctor's Office
- Health Care Facilities
- Hospitals
- Infirmaries
- Nursing Homes
- Physician's Office
- Restrooms

(This product) disinfects hard, non-porous (environmental) surfaces such as:

- Bathroom Fixtures
- Bedside Tables
- Counters
- ~~Dental Instruments~~
- Floors
- Furniture
- Medical Lamps / Stands / Trays
- Non-medical Chrome / Stainless Steel
- Patient Bed Frames
- ~~Surgical Instruments~~
- Walls
- Wheelchairs

<< Terminal Sterilant Statement – qualified metal surfaces >>

This product is not for use on critical & semi-critical medical devices or medical equipment surfaces.

<< Terminal Sterilant Statement – unqualified metal surfaces >>

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 bloodstream 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. This product may be used to pre-clean or decontaminate critical or semi-critical devices prior to sterilization or high level disinfection.

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DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

(This product) is a concentrate. Always dilute in accordance with label instructions. Thoroughly pre-clean all soiled surfaces with (this product) prior to disinfecting.

DILUTION CHART		
To prepare proper dilution, add (this product) full strength to water as below.		
Dilution Ratio	(This product)	Water
0.5% (1:200)	5 cc (1 tsp.)	1 quart
	20 cc (4 tsp.)	1 gallon
	40 cc (1-1/2 fl. oz.)	2 gallons
1.0% (1:100)	10 cc (2 tsp.)	1 quart
	40 cc (1-1/2 fl. oz.)	1 gallon
	80 cc (2-2/3 fl. oz.)	2 gallons
One (1) tablespoon is equivalent to 1/2 fluid ounce or 15 cc.		

NOTE: Prepare a fresh solution of (this product) for each use. If a freshly prepared 0.5% solution of (this product) is not to be utilized immediately, add 2 oz. of Isopropyl alcohol to each quart of (this product) solution to maintain clarity.

For General Cleaning: Use a 0.5% solution for lightly soiled areas and a 1% solution for more difficult soil conditions.

For Hospital Disinfection including Tuberculocidal effectiveness: When required, remove heavy soil and gross filth prior to disinfection as per above Cleaning instructions. Floors, walls and hard, non-porous environmental surfaces should be mopped, wiped or scrubbed with the recommended solution [1:200], maintaining a thoroughly wet surface for 10 minutes and allowed to air dry. Discard used solution daily or more often if soiling is evident. (This product) is effective in 10 minutes at 20°C [68°F]. **For Tuberculocidal Activity,** 0.5% solution (of this product) is effective in 10 minutes at 20°C [68°F].

For Human Immunodeficiency Virus Type 1 [HIV-1 AIDS Virus] Activity: Use at 0.5% dilution – See Dilution Chart.

KILLS HUMAN IMMUNODEFICIENCY VIRUS [HIV-1 AIDS Virus] ON PRE-CLEANED ENVIRONMENTAL SURFACES / OBJECTS PREVIOUSLY SOILED WITH BLOOD / BODY FLUIDS in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces / objects with blood / body fluids; and in which the surfaces / objects likely to be soiled with blood / body fluids can be associated with the potential for transmission of HIV-1 [associated with AIDS].

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 [AIDS Virus] ON SURFACES / OBJECTS SOILED WITH BLOOD / BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood / body fluids, use disposable latex gloves, gowns, masks and eye protection.

CLEANING PROCEDURES: Blood / body fluids must be thoroughly cleaned from surfaces / objects before application of (this product).

CONTACT TIME: Allow surfaces / objects to remain wet for 10 minutes.

DISPOSAL OF INFECTIOUS MATERIALS: Blood / body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

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NOTE: Before using (this product) consult the instrument manufacturer's instructions for care and disinfection of their instruments. (This product) may cause damage to certain types of plastic trays. Refer to manufacturer's instructions for proper use.

Instrument Decontamination: Where appropriate, follow Standard Precautions. (This product) is intended to help prevent protein matter from hardening on instruments and to help reduce exposure to pathogens during the decontamination process.

For Disinfection of Non-Critical Surgical and Dental Instruments / Equipment:

All instruments and devices must be thoroughly cleaned to remove excess debris, rinsed and then rough dried before immersion. Clean and rinse the lumens of hollow instruments before filling with solution. Apply or immerse instruments in (this product) solution for 10 minutes to wet all surfaces thoroughly. Flush and fill the lumen of hollow instruments / equipment, avoiding entrapment of air bubbles. If instruments are to remain in the solution for substantially longer periods of time, add 1 gram of Sodium bicarbonate to each quart of solution; stir to dissolve completely. Also add 2 oz. of Isopropyl alcohol per quart of solution to maintain clarity. Remove and rinse instruments. Wipe dry or allow to air dry prior to use or further processing. Change solution as needed when the solution becomes diluted or visibly soiled.

NOTE: Critical and semi-critical devices must be followed by appropriate sterilization or high-level disinfection process.

Conductive Floors:

Certain areas of a hospital or an industrial plant require that safe level of conductivity be maintained on the floors. The established levels of safe conductivity are between 25,000 – 1,000,000 ohms. Electric discharges must be dissipated rapidly to avoid static discharges that might affect flammable materials, such as anesthetics or sensitive electrical equipment. Using improper disinfectants or detergents can cause a residue formation which can impair conductivity. (This product) has no effect on the resistant properties of conductive flooring as per the requirements of the National Fire Protection Association, NFPA-99-1993, Chapter 12, Section 12-4.1.3.8. Test results are available upon request.

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PRECAUTIONARY STATEMENT: Hazards to Humans and Domestic Animals.

DANGER: Corrosive. Causes eye damage and skin irritation. Do not get in eyes, on skin or on clothing. Wear protective eye wear and rubber gloves when handling. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

FIRST AID	
If in Eyes	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a Poison Control Center or doctor for treatment advice.
If on Skin or Clothing	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a Poison Control Center or doctor for treatment advice.
If Swallowed	<ul style="list-style-type: none">• Call a Poison Control Center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the Poison Control Center or doctor.• Do not give anything by mouth to an unconscious person
CONTACT NUMBER	
Questions? Comments or In case of an emergency call toll free 1-800-677-9218. Have the product container or label with you when calling a Poison Control Center or doctor or going for treatment.	
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	

STORAGE AND DISPOSAL:

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE: Store in original container in areas inaccessible to children. Keep securely closed.

PESTICIDE DISPOSAL: Pesticide wastes may be hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to the label directions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Clean container promptly after emptying. Triple rinse (or equivalent). Follow pesticide disposal instructions for rinsate. Then discard in trash or offer for recycling, if available.

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