

1-15-2004

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675-19



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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 15, 2004

Deanna Gilbreath
Agent for Reckitt Benckiser, Inc.
Scientific & Regulatory Consultants, Inc.
P.O. Box 1014
Columbia City, IN 46725

Subject: Bulk Amphy[®] Brand Disinfectant
EPA Registration No. 675-19
Application Date: November 12, 2003
EPA Received Date: November 20, 2003

Dear Ms. Gilbreath:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

Proposed Amendment

- Update First Aid Statements per PR Notice 2001-1
- Update Precautionary Statements
- Other label changes to comply with recent labeling reviews by Agency
- Change primary brand name to "Bulk Amphy[®] Brand Disinfectant"

Conditions

1. On Page 2, delete the use sites "other institutional facilities" and "other similar equipment." Use sites must be specific and these sites are too broad.
2. On Page 5, revise the Precautionary Statements to read:

CONCURRENCES

SYMBOL	7510C						
SURNAME	Gray						
DATE	1-15-04						

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING: Harmful if swallowed. Causes eye and skin irritation. Do not get in eyes, on skin or on clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

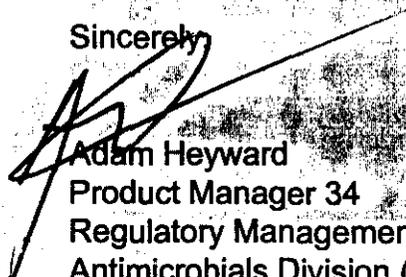
General Comments

As requested, the product primary brand name has been changed from "Bulk Lysol® Brand Disinfectant" to "**Bulk Amphy!® Brand Disinfectant.**" Your records will be changed to reflect the current primary brand name for the subject product.

A stamped copy of the labeling accepted with conditions is enclosed. Submit three(3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please contact me at 703-308-6422.

Sincerely,



Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510 C)

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**BULK
AMPHYL®
BRAND DISINFECTANT**

[GERMICIDAL*] [Staphylocidal] [Pseudomonacidal**] [Tuberculocidal], [Salmonellacidal]
[FUNGICIDAL*] [Against pathogenic fungi]
[VIRUCIDAL*] [Against] [Influenza Virus Type A (Japan)] [Herpes Simplex Type 1] [Vaccinia]
[Adenovirus Type 2] [and] [Human Immunodeficiency Virus Type 1 (HIV-1) (AIDS Virus)]

*On Hard, Nonporous Environmental Surfaces

**At 2% Solution

[Prevents Mold and Mildew]

{For 64 oz. container}
[At 1% dilution, makes 48 gallons]

[Sanitizes Laundry]

[VALUE PACK]

[For Hospital Use]

[For use [only] in Institutional and Industrial Facilities]

[DILUTE AT [1:100], [2:100],[3:100]]

[[FOR USE] [CAN BE USED] [AS] [IN] [USEFUL AS] PART OF [AN] [A FACILITY'S] [ESTABLISHED] INFECTION CONTROL PROGRAM.]]

[[HELPS COMPLETE] [ADDS TO] [ROUNDS OUT] A FACILITY'S [ESTABLISHED] INFECTION CONTROL PROGRAM.]]

[[WORKS] [IS COMPATIBLE] [WITH OTHER RECKITT BENCKISER PROFESSIONAL PRODUCTS] [IN COMBATING CROSS CONTAMINATION] [ON ENVIRONMENTAL SURFACES] [IN THE HEALTH CARE ENVIRONMENT.]]

[[FOR] [USE BY ENVIRONMENTAL SERVICES] [IN COMBATING CROSS CONTAMINATION] [IN A HEALTH CARE FACILITY.]]

ACTIVE INGREDIENTS:

o-Phenylphenol2.80%

o-Benzyl-p-chlorophenol2.70%

OTHER INGREDIENTS:..... 94.50%

TOTAL:..... 100.00%

**ACCEPTED
with COMMENTS
EPA Letter Dated:**

JAN 15 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 675-19

KEEP OUT OF REACH OF CHILDREN

WARNING

Harmful if swallowed. Causes eye and skin irritation.
See Back (Side) Panel for Additional Precautionary Statements

EPA REG. NO. 675-19

EPA EST. NO. {Insert establishment number here} [See bottom [side] panel]

NET CONTENTS: {Insert container size}

Note: Bracketed[] information is optional text. Text separated by a comma(,)denotes-and/or-options.
{Bracketed Text} is for administrative purposes only and will not appear on the printed label.

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[Bulk AMPHYL® Brand Disinfectant] [This product] is recommended for use on hard, nonporous environmental surfaces in:

- [hospitals]
- [nursing homes]
- [dental offices]
- [doctors' offices]
- [other institutional facilities]

[Bulk AMPHYL® Brand Disinfectant] [This product] may be used on:

- | | | |
|-----------------------------|------------------------|---------------|
| • [floors] | • [wheelchairs] | • [furniture] |
| • [walls] | • [patient bed frames] | • [counters] |
| • [bathroom fixtures] | • [bedside tables] | |
| • [surgical instruments] | • [medical lamps] | |
| • [dental instruments] | • [stands] | |
| • [other similar equipment] | • [trays] | |

[BULK AMPHYL® BRAND DISINFECTANT] [THIS PRODUCT] IS IN CONCENTRATED FORM. DILUTE ACCORDING TO DIRECTIONS.

DIRECTIONS FOR USE:

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

DILUTION CHART

To prepare proper dilutions in required quantities, add [this product] full strength [Bulk AMPHYL® Brand Disinfectant] to water as below.		
CORRECT SOLUTION STRENGTH	BULK AMPHYL® BRAND DISINFECTANT	WATER
1% (1:100)	10 cc. 40 cc. 4 fl. oz.	1 quart 1 gallon 3 gallons
2%† (2:100)	80 cc. 8 fl. oz.	1 gallon 3 gallons
3% (3:100)	30 cc. 4 fl. oz. 12 fl. oz. 20 fl. oz.	1 quart 1 gallon 3 gallons 5 gallons
LAUNDRY SANITIZING (1:272)	1 cup	17 gallons

† [This] [A 2%] dilution is to be used whenever bactericidal activity against *Pseudomonas aeruginosa* is desired.

ONE TABLESPOON IS EQUIVALENT TO 1/2 FLUID OUNCE OR 15 CC.

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FOR BROAD SPECTRUM DISINFECTION (Use at 1% Dilution – See Dilution Chart):

To disinfect hard non-porous surfaces, first clean surface thoroughly prior to application of [Bulk AMPHYL® Brand Disinfectant] [this product]. Apply solution to surface using a sponge or mop to wet all surfaces thoroughly. Let stand 10 minutes before wiping or allow to air dry. Fresh solution should be prepared daily or more often if solution becomes diluted or soiled. For tuberculocidal activity, 1% Bulk AMPHYL® Brand Disinfectant is effective in 10 minutes at 20°C (68°F).

FOR MOLD AND MILDEW ON HARD NON-POROUS SURFACES (Use at 1% Dilution – See Dilution Chart):

Wash surfaces with [Bulk AMPHYL® Brand Disinfectant] solution; allow to air dry. Repeat application as necessary.

FOR [USE IN HEALTHCARE SETTINGS] [USE AS A HOSPITAL DISINFECTANT] [HOSPITAL DISINFECTION] OR WHERE PSEUDOMONACIDAL ACTIVITY IS DESIRED (Use at 2% Dilution – See Dilution Chart):

Clean surface thoroughly. Apply solution using a sponge or mop. Wet surfaces thoroughly. Let stand 10 minutes before wiping or let air dry.

FOR HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [(HIV-1)] (AIDS VIRUS) ACTIVITY (Use at 2% Dilution – See Dilution Chart):

KILLS HIV-1 (AIDS VIRUS) ON PRECLEANED 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 surface/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, or eye protection.

CLEANING PROCEDURES: Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of [Bulk AMPHYL® Brand Disinfectant] [this product].

CONTACT TIME: Allow surface to remain wet for 10 minutes.

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

[INSTRUMENT DECONTAMINATION: (Use at 3% Dilution – See Dilution Chart):]

[Where appropriate, follow [Universal] [Standard] Precautions]

[Bulk AMPHYL® Brand Disinfectant] [This product] is intended to help prevent protein matter from hardening on instruments and to help reduce exposure to pathogens during the decontamination process.

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 preclean or decontaminate critical or semi-critical devices prior to sterilization or high level disinfection.

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NOTE: Before using [Bulk AMPHYL® Brand Disinfectant] [this product], consult the instrument manufacturer's instructions for care and disinfection of their instruments. [Bulk AMPHYL® Brand Disinfectant] [This product] may cause damage to certain types of plastic trays. Refer to manufacturer's instructions for proper use.

FOR PRECLEANING OF SURGICAL [AND] DENTAL INSTRUMENTS [AND EQUIPMENT] SURFACES PRIOR TO DISINFECTION: Instruments must be cleaned prior to disinfection to remove all adhering blood and serous exudates, body fluids and human wastes. Apply [Bulk AMPHYL® Brand Disinfectant] [this product] directly, wetting all surfaces thoroughly. Wipe surface with a paper towel. Discard towel.

FOR DISINFECTION OF NON-CRITICAL SURGICAL AND DENTAL INSTRUMENTS [AND EQUIPMENT]:

Apply or immerse instruments in Bulk AMPHYL® Brand Disinfectant solution for 15 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.

FOR SANITARY DISPOSAL OF URINE , FECES:

To urine, add equal amount of Bulk AMPHYL® Brand Disinfectant solution. For feces, place [3% Bulk AMPHYL® Brand Disinfectant] solution in pan in amount slightly larger than expected discharge. After receiving feces, mix thoroughly with solution then cover and let stand for one hour before disposal.

FOR SANITARY LAUNDRY, LINENS, BLANKETS AND DIAPERS (See Dilution Chart):

To each 10 pounds of blankets or linen, introduce 17 gallons of water. Add 1 cup (8 fl. oz.) of [Bulk AMPHYL® Brand Disinfectant] [this product]. Agitate for a minimum of 3 minutes to ensure saturation. Allow to soak for 10 minutes, then add soap or detergent and wash in usual manner.

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CONDUCTIVE FLOORS:

Certain areas of a hospital or an industrial plant require that a 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. [Bulk AMPHYL® Brand Disinfectant] [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.

PRECAUTIONARY STATEMENTS

Hazards to humans and domestic animals

WARNING: Harmful if swallowed. Causes eye and skin irritation. Do not get in eyes. Avoid contact with eyes and skin. Avoid contamination of food.

FIRST AID	
If swallowed	<ul style="list-style-type: none">• Call 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
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.
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.	

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STORAGE AND DISPOSAL {For sizes 1 gallon or less}

Store in original container in areas inaccessible to small children. Keep securely closed. Do not reuse empty container. Rinse thoroughly with water and detergent. [Wrap and] Discard in trash.

{For sizes over 1 gallon}

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal.

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

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

{For sizes 5 gallons or more}

ENVIRONMENTAL HAZARDS

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.

[Please encourage your state and local authorities to establish a recycling program so that this [container] [bottle] [pail] [drum] can be recycled.]

{For 55 gallon size:}

[This label is printed on ___% recycled paper (___% post consumer)]

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

Questions? Comments? Call 1-800-677-9218.

[Monday – [thru] Friday, 8:45 a.m. – [to] 4:30 p.m. [Eastern time].]

[Visit us at www.reckittprofessional.com]

[Distributed by:]



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