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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

NOV 2 1995

Calgon Vestal Laboratories
P.O. Box 147
St. Louis, MO 63166-0147

Attn: George Mell
Regulatory Specialist

Subject: Powder Keg
EPA Registration No. 1043-77
Amendment Dated August 8, 1995

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to clarify the meaning of the HIV-1 claim by placing the associated use-dilution ratios in the cleaning directions, is acceptable, provided that you make the following change listed below before you release the product for shipment bearing the amended labeling.

- Include the EPA/FDA MOU disclaimer statement as per PR Notice 94-4 (copy enclosed).

A stamped copy of the labeling is enclosed for your records. Submit one (1) copy of the final printed label prior to release of the product for shipment.

If you have any questions concerning this letter, please contact Martha Terry at (703) 305-6982.

Sincerely,



Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

Enclosure

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

DANGER

DO NOT REMOVE PACKETS BEFORE USE

Caution: Causes eye and skin damage. Do not get powder in eyes, on skin or on clothing. Harmful if swallowed. Handle only with dry hands. Do not open packets; place directly into bucket.

FIRST AID: In case of eye contact immediately flush with water for 15 minutes and get 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 SURFACES: For routine cleaning and disinfection add one packet to a wash bucket for each measured gallon of warm (70°-80°) water used (1:256 use solution). When making solutions in hard water, use two packets for each measured gallon of warm (70-80°) water used (1:128 use solution). Always gently mix for a uniform solution.

Apply solution with a cloth, sponge, mop or brush using normal cleaning methods. Allow treated surfaces to soak for 10 minutes, then remove excess solution with a wrung-out applicator. Gross filth should be removed by scraping or sweeping before cleaning begins. A fresh solution should be prepared at least daily or more often if the solution becomes diluted or soiled. Powder Keg is a complete product. Do not add water or other chemicals. Use only as directed.

USE ONE PACKET FOR EACH GALLON OF WARM WATER FOR REGULAR CLEANING. WHEN MAKING SOLUTIONS IN HARD WATER USE TWO PACKETS PER GALLON OF WATER.

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 or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type-1 (HIV-1) (associated with AIDS).

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 **POWDER KEG**

Contact Time: While the HIV-1 virus is inactivated in 1 minute, use 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.

STORAGE AND DISPOSAL

Store in a cool dry place. Close this container after each use. Handle packets only with dry hands.

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 solution or rinsings from empty containers should be disposed of in a toilet or service sink served by a sanitary sewer or in a land fill approved for pesticides.

CONTAINER DISPOSAL: Triple rinse and deposit in a waste container for incineration or burial in a land fill approved for pesticide containers.

GENERAL: Consult Federal, State or Local disposal authorities for approved methods and procedures such as limited open burning.

PREMEASURED
GERMICIDAL DETERGENT

POWDER KEG

EPA Reg. NO. 1043-77

Germicide • Deodorizer

Fungicide • Virucide* • Detergent

Active Ingredients:

Octyl Decyl Dimethyl Ammonium Chloride	3.25%
Dioctyl Dimethyl Ammonium Chloride	1.63%
Didecyl Dimethyl Ammonium Chloride	1.63%
n-Alkyl (60% C ₁₄ , 30% C ₁₆ , 5% C ₁₂ , 5% C ₁₈)	
Dimethyl Benzyl Ammonium Chloride	3.16%
n-Alkyl (68% C ₁₂ , 32% C ₁₄)	
Dimethyl Ethylbenzyl Ammonium Chloride	3.16%
Inert Ingredients:	87.17%

DANGER

KEEP OUT OF REACH OF CHILDREN

STATEMENT OF PRACTICAL TREATMENT

In case of eye contact, flush with warm water for 15 minutes. Get medical attention. For skin contact, flush thoroughly with water. See side panel for additional precautionary statements.

Classified by Underwriters Laboratories[®] Inc. as to electrical conductivity when used on conductive floors and spontaneous heating. **POWDER KEG** germicidal detergent—For use with listed electrically conductive flooring of the vinyl type. 942P.

NET WEIGHT: 27 lb. 8 oz. (12.5 kg)

(880 half-ounce water soluble packets)

ACCEPTED
with COMMENTS
in EPA Letter Dated

NOV 2 1995



Under the Federal Insecticide, Fungicide, and Rodenticide Act, amended, for the pesticide registered under EPA Reg. No. 1043-77
CALGON VESTAL LABORATORIES, INC.
A DIVISION OF **MERCK**
LABORATORIES
P.O. BOX 100
ST. LOUIS, MISSOURI 63110

6394-90



3043

POWDER KEG is a concentrated powdered hard-water effective phosphate-free germicidal detergent which is packaged in handy premeasured 1/2 ounce soluble packets. The use-solution made by dissolving one packet per gallon of warm water (70°-80°F) simultaneously cleans and deodorizes while disinfecting.

It is designed for cleaning and disinfecting of washable non-porous hard surfaces such as floors and walls. It is intended for use only in institutions such as hospitals, nursing homes, schools, industrial plants, medical and dental offices, veterinary clinics, and other public areas. It may be used for the cleaning and disinfecting of stainless steel, chrome, glass, porcelain, tile, terrazzo and resilient vinyl, linoleum, asphalt or rubber flooring, as well as washable painted and varnished surfaces.

GERMICIDAL: Passes A.O.A.C. Germicidal Use Dilution Method (*S. aureus*, *S. choleraesuis*, *Ps. aeruginosa*) 10 minutes, in the presence of 5% organic soil (serum) at 20°C, 1:256 dilution, (1:128 in 400 ppm hard water).

BROAD SPECTRUM DATA: In addition, the following organisms pass the A.O.A.C. use-dilution test, 10 minutes, in the presence of 5% organic soil (serum) at 20°C, 1:256 dilution (1:128 in 400 ppm hard water).

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| <i>Acinetobacter calcoaceticus</i> , ATCC 19606 | <i>Salmonella typhimurium</i> , ATCC 14028 |
| <i>Candida albicans</i> , Clinical Isolate | <i>Serratia marcescens</i> , ATCC 8100 |
| <i>Candida parapsilosis</i> , Clinical Isolate | <i>Shigella flexneri</i> , ATCC 12022 |
| <i>Citrobacter freundii</i> , ATCC 8090 | <i>Shigella sonnei</i> , ATCC 25931 |
| <i>Enterobacter aerogenes</i> , ATCC 13048 | <i>Staphylococcus aureus</i> , ATCC 25923 |
| <i>Enterobacter cloacae</i> , ATCC 23355 | <i>Staphylococcus aureus</i> (MRSA), Multiply (Methicillin)-Resistant Clinical Isolate |
| <i>Escherichia coli</i> , ATCC 25922 | <i>Staphylococcus epidermidis</i> , ATCC 12228 |
| <i>Klebsiella pneumoniae</i> , ATCC 13883 | <i>Streptococcus faecalis</i> , ATCC 19433 |
| <i>Proteus mirabilis</i> , Clinical Isolate | <i>Streptococcus pyogenes</i> , ATCC 19615 |
| <i>Proteus vulgaris</i> , ATCC 13315 | |
| <i>Pseudomonas aeruginosa</i> , ATCC 27853 | |

FUNGICIDAL: Passes A.O.A.C. Fungicidal Test (*T. mentagrophytes*) 1:256 dilution, 10 minutes, in the presence of 5% organic soil (serum) at 20°C (1:128 in 400 ppm hard water).

VIRUCIDAL: Passes Virucidal Qualification Test [Influenza A₁ (Hong Kong), Herpes simplex Types 1 and 2, Vaccinia] 1:256 dilution, 10 minutes exposure time in the presence of organic soil (serum) at 20°C, (1:128 in 400 ppm hard water).

POWDER KEG is effective against Adenovirus Type 2 at 1:128 dilution (2 packets per gallon) in 400 ppm A.O.A.C. hard water in the presence of 5% organic soil (serum) in 10 minutes at 20°C.

When tested by an EPA-approved Dilution Method, the HIV-1 (AIDS) virus, with added 10% organic soil (serum), was completely inactivated by a 1:256 (1 packet per 1 gallon) solution in 60 seconds at 20°-25° 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-COUNTERACTANT: **POWDER KEG** attacks odors in three ways by killing odor-causing bacteria, chemically neutralizing odor residues, and with fine detergent cleaning ingredients.

EPA Est. No. 35772-IL-1

6394-90C(194)
PRODUCT MADE IN USA

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV 2 1995

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

1043-77

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