

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 4 1996

Central Solutions, Inc.
P.O. Box 15276
3130 Brinkerhoff Road
Kansas City, KS 66115

Attention: Paul Nobrega
Registration Specialist

Subject: Q 4.5-5.0 PB-4.5
EPA Registration No. 211-40
Your Amendment Dated April 4, 1996
EPA Received Date April 18, 1996

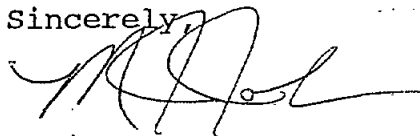
The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to add a Non-Food Contact Surface Sanitization efficacy claim against Enterobacter aerogenese (ATCC 13048) and Staphylococcus aureus (ATCC 6538), has been reviewed by the Agency and found to be acceptable, provided you make the following labeling changes before you release the product for shipment bearing the amended labeling.

1. On page 4, relocate the yeast, Candida albicans under the heading "FUNGICIDAL".
2. On page 4, change "GERMICIDAL" to read "BACTERICIDAL" because only tested bacteria will be listed under this heading after you relocate Candida albicans.

A stamped copy of the Q 4.5-5.0 PB-4.5 product labeling is enclosed for your records. Submit one (1) copy of the final printed labeling before you release the product for shipment.

If you have any questions concerning this letter, please contact Doreen Aviado of my staff at (703) 305-6554.

Sincerely,



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

CONCURRENCES

SYMBOL	Enclosure	7505C	7505C					
SURNAME		D. Aviado	M. Johnson					
DATE		9/11/96	10/3/96					

295

ACCEPTED
with COMMENTS
in EPA Letter Dated:
OCT 4 1996

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide
registered under EPA Reg. No.
211-40

Q4.5-5.0PB-4.5

DISINFECTANT - DEODORIZER - FUNGICIDE - VIRUCIDE*
WHIRLPOOL CLEANER DESIGNED FOR HOSPITAL,
NURSING HOME, AND INSTITUTIONAL USE

Active Ingredients:

n-Alkyl (60%C ₁₄ , 30%C ₁₅ , 5%C ₁₂ , 5%C ₁₈) dimethyl benzyl ammonium chlorides.....	2.25%
n-Alkyl (68%C ₁₂ , 32%C ₁₄) dimethyl ethylbenzyl ammonium chlorides.....	2.25%
Inert Ingredients:.....	95.50%
Total:	100.00%

KEEP OUT OF REACH OF CHILDREN
DANGER
SEE LEFT PANEL FOR ADDITIONAL
PRECAUTIONARY STATEMENTS



CENTRAL SOLUTIONS, INC.

P.O. BOX 15276
3130 BRINKERHOFF ROAD
KANSAS CITY, KS 66115

EPA REG. NO. 211-40
EPA EST. NO. 211-KS-1

NET CONTENTS GAL

(Left Panel)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER

Keep Out of Reach of Children. Corrosive. Causes severe eye and skin damage. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. Wear goggles or face shield and rubber gloves when handling. Avoid contamination of food. Remove and wash contaminated clothing.

STATEMENT OF PRACTICAL TREATMENT

In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash all contaminated clothing before reuse. If swallowed, drink large quantities of water. Call a physician.

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 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.

STORAGE AND DISPOSAL

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

STORAGE - Store in securely closed original container. Store in area that will prevent cross contamination of other pesticides, fertilizer, food, and feed. Avoid storage at temperature extremes or in sunlight.

PESTICIDE DISPOSAL - Pesticide wastes are acutely hazardous. Improper disposal of excess pesticides is in violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your Pesticide or Environmental Control Agency, or the hazardous waste representative at the nearest EPA Regional Office for guidance.

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.

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 blood stream or normally sterile areas of the body, or (2) contact 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 medical devices prior to sterilization or high-level disinfection.

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PRODUCT COMPOSITION

Q4.5-5.0PB-4.5 is a disinfectant, deodorizer, fungicide, and virucide* cleaner designed for hospital, nursing home, and institutional use. Q4.5-5.0PB-4.5 contains two highly active twin chain quaternary ammonium compounds (listed as active ingredients) for bactericidal efficacy. Inert ingredients include a balance of alkaline builders, non-ionic surfactants, and odor counteractants to enhance the cleaning and odor control characteristics. This formulation is designed to clean and disinfect bathing and therapy equipment. When used as directed, Q4.5-5.0PB-4.5 has been found effective for use on all fiberglass, stainless steel, and chrome plated surfaces of bath, therapy, whirlpools, and patient transfer equipment.

DIRECTIONS FOR USE

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

DISINFECTION: To disinfect hard, non-porous, inanimate surfaces (such as fiberglass and stainless steel tubs and chair surfaces, chrome plated intakes and lifts, etc.), apply properly diluted Q4.5-5.0PB-4.5 with mop, cloth sponge, mechanical sprayer, or hand pump trigger sprayer so as to wet all surfaces thoroughly. For routine disinfection, proper dilution is 2 ounces of Q4.5-5.0PB-4.5 per gallon of water (1:64). Allow to remain wet for 10 minutes and then let air dry. For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh dilution for each use.

SANITIZATION: To sanitize non-porous, non-food contact surfaces, add 2 ounces of Q4.5-5.0PB-4.5 per gallon of water (1:64). Treated surfaces must remain wet for 30 seconds.

FOR CLEANING FIBERGLASS BATH AND THERAPY EQUIPMENT: To remove body oils, dead tissue, hard water, and all other buildups or organic matter on inanimate surfaces after using the whirlpool unit, drain the water and refill with fresh water to just cover the intake valve. Add two ounces of Q4.5-5.0PB-4.5 for each gallon of water in the unit at this point. Briefly start the pump to circulate the solutions. Turn off pump. Wash down the unit sides, seat of the chairlift, and any/all related equipment with a clean swab or sponge. After the unit has been thoroughly cleaned, drain solutions from the unit and rinse any/all cleaned surfaces with fresh water. The unit is ready for re-use. Product to surface contact time must be at least 10 minutes for proper disinfection.

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PERFORMANCE DATA

Efficacy tests have demonstrated that Q4.5-5.0PB-4.5 is an effective bactericide, fungicide, and virucide* on hard, non-porous, inanimate surfaces in the presence of moderate amounts of organic soil (5% blood serum). Germicidal, fungicidal, and virucidal* testing has been performed using A.O.A.C. protocol testing as required by the EPA at a use-dilution of 1:64 (two ounces per gallon of water) in the presence of 5% blood serum (used to simulate organic soil load), at 20 degrees celcius with an exposure time of 10 minutes.

GERMICIDAL

The broad spectrum activity of Q4.5-5.0PB-4.5 has been confirmed against the following organisms:

- | | |
|--|-------------------------|
| Pseudomonas aeruginosa | Staphylococcus aureus |
| Escherichia coli | Klebsiella pneumoniae |
| Serratia marscenscens | Salmonella choleraesuis |
| Proteus vulgaris | Candida albicans |
| Methicillin resistant Staphylococcus aureus (MRSA) | |

FUNGICIDAL

Q4.5-5.0PB-4.5's efficacy as a fungicide has been confirmed through testing against the following pathogenic fungi:

- Trichophyton mentagrophytes

VIRUCIDAL

*Testing of Q4.5-5.0PB-4.5 has confirmed its virucidal activity against the following viruses:

- Influenza A2-Asian.....(representative of the common flu virus)
- Herpes simplex Type 1...(causative agent of fever blisters)
- Adeno virus type 2.....(causative agent of upper respiratory infections)
- Vaccinia virus.....(representative of the pox virus group)
- HIV-1.....(AIDS Virus)

KILLS HIV-1 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 inanimate surfaces/objects likely to be soiled 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). Contact time: ten (10) minutes.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST AIDS (HIV-1 VIRUS) ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS WITH TEN (10) MINUTE CONTACT TIME.

PERSONAL PROTECTION: Disposable gloves should be worn when cleaning blood, body fluids, or contaminated items. Hands should be washed immediately and thoroughly after gloves are removed, or if hands are contaminated with blood or body fluids. Masks and protective eyewear or faceshields should be worn during cleaning procedures involving blood or body fluids. Gowns or aprons should be worn during leaning procedures for protection against splashes of blood or other body fluids.

CLEANING PROCEDURE: Blood and other fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant. After cleaning is complete, follow disinfection described previously.

DISPOSAL OF INFECTIOUS MATERIALS: Contaminated waste and blood and other body fluids, should be autoclaved and disposed according to local regulations for infectious waste disposal.

SANITIZATION

At a use-dilution of 1:64 (2 ounces per gallon of water), in 400 ppm hardwater, Q4.5-5.0PB-4.5 is an effective sanitizer on non-porous, non-food contact surfaces against the following organisms:

- Staphylococcus aureus
- Enterobacter aerogenes

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