

303-226

5-1-2000

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 0 1 2000

Huntington Professional Products
Service of ECOLAB Inc.
370 N. Wabasha Street
St. Paul, MN 55102

ATTENTION: Brian Brosdahl

SUBJECT: QUAT 64
EPA Registration Number 303-226
Your Amendment Dated: January 21, 2000
EPA Received Date: February 1, 2000

The amendment referred to above, submitted in connection with registration under FIFRA as amended, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling:

A. A "Pesticide Storage" statement is required as per PR Notice 83-3. Revise the label to include the following "Pesticide Storage" statement:

"Pesticide Storage: Store in tightly closed container in a secure area inaccessible to children and away from food or feed."

B. The label on file with the Agency must be a master label which includes all possible language for this product. Those statements which will only appear on specific sized containers are prefaced with comments (i.e. "for 5 and 55 gallon containers"). Revise your label to state "for 5 and 55 gallon containers" immediately preceding the Environmental Hazards Statement as well as the set of Storage and Disposal statement which include Pesticide Storage, Pesticide Disposal, and Container Disposal statements.

C. Add the following combined "Storage and Disposal" Statement as the only storage and disposal text required on containers of one gallon or less: (This statement is appropriate due to the fact that this product is for use in schools.)

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"For containers 1 gallon or less:

Storage and Disposal: Store in tightly closed container in a secure area inaccessible to children and away from food or feed. Do not reuse empty container. Wrap container and discard in trash."

D. As per Subdivision H: Labeling Guidelines for Pesticide Use Directions for Antimicrobial Products, section 101-3, p.25 your label must include the following directions for use as a fungicide.

"Fungicidal Instructions: Will effectively control the growth of *Trichophyton mentagrophytes* on hard nonporous shower room floors and locker room benches at a dilution of 1:64 with a contact time of 10 minutes. Apply as directed for disinfecting."

E. Since the front panel of your label states that this product is a deodorizer and detergent your label must have separate "Directions for Use" as a cleaner and deodorizer as per DIS/TSS-15. Include the following language on your label:

"Cleaning and Deodorizing Instructions: Apply solution at a dilution of 1:64 with a cloth, mop, coarse spray device or by soaking. Remove solution with a clean wet mop, cloth or wet vacuum pickup or allow to air dry."

F. Your resubmission includes the site "Barns." Thus your label must include the following set of directions as per DIS/TSS-18. The following label directions are required for farm premises disinfectants to permit their classification as non-food use products:

"Disinfection Directions for use in Barns:

1. Remove all animals and feed from premises, vehicles, and enclosures.
2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks, and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent and rinse with water.
5. Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.
6. Immerse all halters, ropes, and other types of equipment used in handling and restraining animals, as well as forks, shovels, and scrapers used for removing litter and manure.

7. ~~Ventilate buildings, pens, troughs, and other closed spaces. Do not house~~

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livestock or employ equipment until treatment has been absorbed, set, or dried.

- 8. *Thoroughly scrub all treated feed racks, mangers, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse."*

G. The directions for use in Animal Housing Facilities, Veterinary Clinics and Animal Life Science Laboratories must read as follows.

"Disinfection and Deodorizing of Animal Housing Facilities, Veterinary Clinics and Animal Life Science Laboratories (Kennels, Cages and Hutches): (deleting the abbreviation "etc." which follows the surfaces "hutches".)

- 1. *Remove all animals and feed from premises.*
- 2. *Remove all litter and manure from floors, walls surfaces and fixtures occupied or traversed by animals.*
- 3. *Empty all feeding and watering appliances.*
- 4. *Thoroughly clean all surfaces with soap or detergent and rinse with water.*
- 5. *Saturate all surfaces with the recommended disinfecting solution for a period of 10 minutes.*
- 6. *Immerse all types of equipment used in handling and restraining animals, and scrapers used for removing litter and manure.*
- 7. *Ventilate buildings and allow surfaces to air dry before reintroducing animals.*
- 8. *Thoroughly scrub all feeding and watering appliances with soap or detergent, and rinse with potable water before reuse."*

H. Revise the first sentence of the "Use Directions for Disinfecting" to read exactly as follows. Your label must list specific sites and surfaces.

"For use on hard, nonporous environmental surfaces such as: floors, walls, metal surfaces, stainless steel surfaces, glazed ceramic tile, glazed porcelain, and plastic surfaces (polypropylene, polystyrene)."

Deleting the phrase "and other nonporous environmental surfaces."

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I. The submitted pictogram, a picture of microorganisms with a slash through them, has been examined by the regulatory team as well as the efficacy team at the Agency. This graphic is unacceptable based on PR Notice 95-2 section II (A), the Label Review Manual, Chapter 14 as well as the regulatory and efficacy teams. This product is a disinfectant and thus does not kill all organisms as is implied by your graphic. This graphic has been "blocked-out" on the stamped copy of the label and the same must be done on the labels which you print. This graphic may not appear on the label used to market this product.

J. Upon your next submission of this label for amendment, revise your label such that it identifies the specific antibiotic resistance of each organisms claimed on your label. If all of the organisms identified with a 1 superscript are resistant to the same antibiotic then list that antibiotic as part of the superscript. The same applies to the superscript 2. Alternatively the antibiotic resistance must be identified specifically in parenthesis after each appropriate organism. Upon resubmission, this information will be reviewed by our efficacy team to verify that your referenced studies support these specific microorganisms.

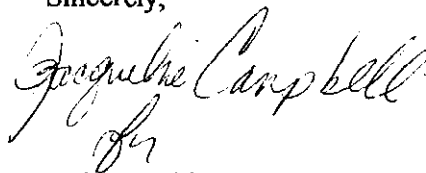
K. Place the following statement immediately below the signal word on the front panel of the label:

"See side panel for additional precautionary and statements and statement of practical treatment."

2. Submit two (2) copies of your final printed labeling before you release the product for shipment. A stamped copy of the labeling is enclosed for your records.

Should you have any questions concerning this letter, please contact Tracy Lantz at (703) 308-6415.

Sincerely,



Velma Noble
Product Manager (31)
Regulatory Management Branch I
Antimicrobials Division (7510C)

Enclosure (stamped label)

7510C.T. Lantz:4/27/00.303-226c

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Huntington
brand

DISINFECTANT

QUAT 64

Germicidal Detergent
Disinfectant/deodorizer/fungicide/
virucide*/detergent

ACCEPTED
with COMMENTS
in EPA Letter Dated:

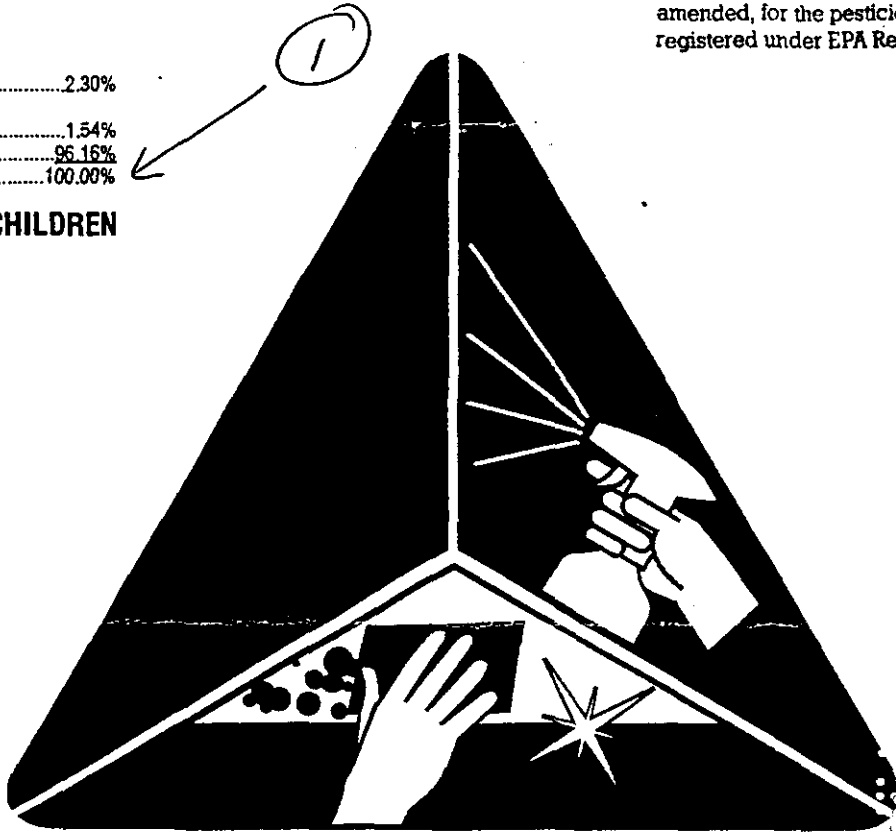
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Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. *303-226*

ACTIVE INGREDIENTS:

Didecyl Dimethyl Ammonium Chloride2.30%
n-Alkyl (C ₁₁ , 50%; C ₁₂ , 40%; C ₁₃ , 10%)	
Dimethyl Benzyl Ammonium Chloride1.54%
INERT INGREDIENTS:96.16%
TOTAL:100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION



ECOLAB[®]

Net Contents: 55 U.S. gal/208 L

EPA Reg. No. 303-226
EPA Est. 303-IN-1 (L), 1677-IL-2 (J), 1677-NJ-1 (W), 1677-TX-1 (C),
1677-GA-1 (M), 1677-MN-1 (P), 1677-CA-1 (S), 1677-PR-1 (B),
1677-OH-1 (H)

Superscript refers to first letter of date code.

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PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Harmful if inhaled. Avoid breathing spray mist. Causes moderate eye irritation. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.
IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.
IF IN EYES: Flush with plenty of water. Call a physician if irritation persists.
FOR EMERGENCY MEDICAL INFORMATION CALL: 1-800-328-0026.

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 Pollution 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.

QUAT 64 is a multi-purpose germicidal detergent and deodorant effective when diluted 1:64 in up to 400 ppm hard water (calculated as CaCO₃) plus 5% organic serum according to the AOAC Use-dilution and virucidal qualification tests. Disinfects, cleans, and deodorizes in one labor-saving step. Recommended for use in hospitals, nursing homes, schools, colleges, veterinary clinics, animal life science laboratories, federally inspected meat and poultry establishments and breeding establishments.

Effective against the following pathogens on hard, nonporous, inanimate surfaces when diluted 1:64 (2 oz. per 1 gallon):

Bactericidal against: *Pseudomonas aeruginosa*¹, *Staphylococcus aureus*¹, *Salmonella choleraesuis*, *Acinetobacter calcoaceticus*, *Bordetella bronchiseptica*, *Chlamydia psittaci*, *Enterobacter aerogenes*, *Enterobacter cloacae*, *Escherichia coli*¹, *Fusobacterium necrophorum*, *Klebsiella pneumoniae*¹, *Legionella pneumophila*, *Listeria monocytogenes*, *Pasteurella multocida*, *Proteus mirabilis*, *Proteus vulgaris*, *Salmonella enteritidis*, *Salmonella typhi*, *Salmonella typhimurium*, *Serratia marcescens*, *Shigella flexneri*, *Shigella sonnei*, *Staphylococcus aureus* (methicillin resistant), *Staphylococcus epidermidis*², *Streptococcus faecalis*¹, *Streptococcus pyogenes*, *Enterococcus faecalis* (vancomycin resistant), *Staphylococcus aureus* (vancomycin resistant).

Virucidal against: *Adenovirus type 4, *Canine distemper, *Feline leukemia, *Feline picornavirus, *Herpes simplex type 1, *Herpes simplex type 2, *HIV-1 (AIDS virus), *Infectious-bovine rhinotracheitis, *Infectious bronchitis (Avian IBV), *Influenza A/Hong Kong, *Pseudorabies, *Rabies, *Respiratory syncytial virus (RSV), *Rubella (German Measles), *Transmissible gastroenteritis virus (TGE), *Vaccinia.

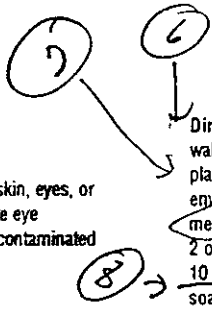
Fungicidal against: *Aspergillus niger*, *Candida albicans*, *Trichophyton mentagrophytes*.

1 ATCC & antibiotic-resistant strain.
2 antibiotic-resistant strain only.

Dilution: 1 to 64 (2 oz. per gallon)

DIRECTIONS FOR USE

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



Directions For Disinfecting: For use on hard, nonporous surfaces such as floors, walls, metal surfaces, stainless steel surfaces, glazed ceramic tile, glazed porcelain and plastic surfaces (such as polypropylene, polystyrene, etc.) and other nonporous environmental surfaces. Not for use on food preparation surfaces, medical devices or medical equipment surfaces. Remove gross filth and heavy soil deposits. Using 2 ounces per gallon of water, thoroughly wet surfaces for a minimum contact time of 10 minutes. Can be applied with a cloth, mop, sponge, coarse spray device or by soaking. The recommended use solution is prepared fresh for each use then discarded. Remove solution and entrapped soil with clean wet mop, cloth or wet vacuum pickup, or allow to air dry. Rinsing is not necessary unless used on floors that are to be waxed or polished.

Disinfection And Deodorizing Of Animal Housing Facilities (Barns, Kennels, Cages, Hutches, Etc.)
Remove animals and feed from facilities. Remove litter, waste matter and gross soils. Empty all troughs, rack and other feeding and watering equipment. Disinfect surfaces as described under Directions For Disinfecting. Ventilate buildings and other closed spaces. Allow to air dry before reintroducing animals.

USDA: For use in federally inspected meat and poultry plants on all hard, nonporous surfaces in inedible product processing areas, nonprocessing areas, and/or exterior areas.
Mildewstatic Instructions: Will effectively control the growth of mold and mildew plus the odors caused by them when applied to hard, nonporous surfaces such as walls, floors, and table tops. Apply solution (2 ounces per gallon of water) with a cloth, mop, sponge, or coarse spray. Make sure to wet all surfaces completely. Let air dry. Repeat application weekly or when growth reappears.

***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 surfaces/objects likely to be soiled with blood/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 (AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS
Personal Protection: Disposable latex or vinyl gloves, gowns, face masks, or eye coverings as appropriate must be worn during all cleaning of blood/body fluids and during decontamination procedures.

Cleaning Procedure: Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of disinfectant.

Contact Time: HIV-1 (AIDS virus) is inactivated after a contact time of 4 minutes at 25°C (room temperature). Use a 10 minute contact time for other viruses, fungi, and bacteria listed.

Disposal of Infectious Materials: Blood/body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.

STORAGE AND DISPOSAL

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

Pesticide Disposal: Waste 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 incinerate, or, if allowed by state and local authorities, burn. If burned, stay out of smoke.

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For product information, call 1-800-332-6522.

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ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 01 2000



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