

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 15 1996

Huntington Laboratories, Inc.
970 East Tipton Street
Huntington, IN 46750

Attention: Sally Hayes
Regulatory Affairs Manager

Subject: Ascend
EPA Registration No. 303-209
Q-Cide
EPA Registration No. 303-210
Quat 64
EPA Registration No. 303-226

Amendments Dated March 18, 1996

The amendments referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), to add disinfection claims against Enterococcus faecalis - Vancomycin Resistant on hard, nonporous inanimate surfaces in the presence of 5% fetal bovine serum and 400 ppm of synthetic hard water when used at a dilution of 1:256 (0.5 ounce/gallon) (providing 600 ppm of active quaternary) when thoroughly wetted and allowed to remain wet for a contact time of at least 10 minutes are acceptable provided that you comply with the items below.

1. Submit/cite all data required for registration/reregistration of your products under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit five (5) copies of your final printed labeling before you release the products for shipment.

| CONCURRENCES | | | | | | | |
|--------------|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
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If these conditions are not complied with, the registrations will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the products constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

Sincerely yours,

Marion J. Johnson
Product Manager 31
Antimicrobial Programs Branch
Registration Division (7505C)

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QUAT 64

GERMICIDAL DETERGENT

Disinfectant · Deodorizer · Fungicide
*Virucide · Detergent

Active Ingredients:
Didecyl dimethyl ammonium chloride 2.30%
n-Alkyl (C₁₄ 50%, C₁₂ 40%, C₁₆ 10%)
dimethyl benzyl ammonium chloride 1.54%
Inert Ingredients: 96.16%

KEEP OUT OF REACH OF CHILDREN

CAUTION

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.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes eye irritation. Avoid contact with eyes. Wash thoroughly after handling.

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.

Net Contents: _____

EPA Reg. No. 303-226 EPA Est. No. 303-IN-1

Huntington Laboratories, Inc. · Huntington, IN 46750 · (219) 356-8100
Lansdale, PA 19446 · Denver, CO 80205 · Dallas TX, 75227
Oakland, CA 94621 · Bramalea, Ontario, Canada L6T 1E3

(Directions for Use continued)

*Kills HIV-1 (AIDS virus) on precleaned, environmental surfaces/objects previously soiled with blood/body fluids in healthcare 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 I (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 Procedures: 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

PROHIBITIONS

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty container.

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

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, hotels, motels, veterinary clinics, animal life science laboratories, federally inspected meat and poultry establishments, poultry farms, turkey farms, dairy farms, hog farms, and breeding establishments.

Effective against the following pathogens on hard, non-porous, inanimate surfaces when diluted 1:64 (2 oz. to 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)

Virucidal against:

*Adenovirus type 4
*Avian polyomavirus
*Canine distemper
*Canine parvovirus
*Feline leukemia
*Feline panleukopenia
*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
*Porcine parvovirus
*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 strains
² antibiotic-resistant strains

ACCEPTED
With COMMENTS
EPA Letter Dated:
OCT 15 1996
Under the Federal Insecticide, Fungicide and Rodenticide Act
registered with the Pesticide Act
EPA Reg. No.
303-226-0000 POUNDS PER GALLON

DILUTION: 1 to 64

DIRECTIONS FOR USE

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

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.

GENERAL USE DIRECTIONS FOR DISINFECTING:

For use on hard, non-porous surfaces such as floors, walls, metal surfaces, stainless steel surfaces, glazed ceramic tile, glazed porcelain, rubber and plastic surfaces (such as polypropylene, polystyrene, etc.) and other hard, non-porous environmental surfaces. Remove gross filth and heavy soil deposits then thoroughly wet surfaces. Use 2 ounces per gallon of water for a minimum contact time of 10 minutes. Can be applied with a cloth, mop, sponge, coarse spray or by soaking. The recommended use solution is prepared fresh for each use then discarded. Rinsing is not necessary unless used on floors that are to be waxed or polished.

USDA: For use in federally inspected meat and poultry plants or all hard, non-porous surfaces in inedible product processing areas, non-processing 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, non-porous 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.

031296

BEST AVAILABLE COPY

(label continued)

QUAT 64

GERMICIDAL DETERGENT

FARM PREMISE, LIVESTOCK, POULTRY & TURKEY HOUSE DISINFECTANT

DILUTION: 1:64 2 OUNCES PER GALLON OF WATER

DIRECTION FOR USE

1. Remove all animals and feeds from premises, trucks, coops, crates, and enclosures.
2. Remove all litter and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, vehicles, 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, coops, cars, boats, and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set, or dried.
8. After treatment with disinfectant, thoroughly scrub feed racks, troughs, automatic feeders, fountains, and waterers with soap or detergent, and rinse with potable water before reuse.

[May be used as a box insert and/or hang tag.]

031296

ACCEPTED
with COMMENTS
in EPA Letter Dated:
OCT 15 1996

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

303-224