

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Mr. Troy Munson
Athea Laboratories, Inc.
P.O. Box 240014
Milwaukee, WI 53224

DEC 23 2002

Subject: Neu-Quat 64
EPA Registration No. 10088-106
Amendment Date: September 30, 2002
EPA Receipt Date: October 4, 2002

Dear Mr. Munson,

The following amendment submitted in connection with registration under FIFRA, as amended, is acceptable.

- Response to Agency letter dated July 29, 2002

Conditions

Revise the label as follows:

Under the disinfection directions, you must either state that the product must "air dry" or "excess solution be removed after the contact time" according to DIS/TSS

General Comments

The Confidential Statement of Formula dated 7/16/02 is acceptable. It is in compliance with the label and PR Notice 91-2.

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 regarding this letter, please contact Jacqueline McFarlane at (703) 308-6416.

Sincerely,


Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

DANGER: Corrosive. Causes irreversible eye damage. Harmful if inhaled. Avoid breathing spray mist. Harmful if absorbed through skin. Avoid contact with skin. Do not get in eyes or on clothing. Wear protective eyewear(goggles, face shield, or safety glasses). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID

IF IN EYES: 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: 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.

IF SWALLOWED: Call a 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information on this pesticide (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378. For information on product, usage, etc., call 1-800-743-6417

Environmental Hazards (5 gallons or greater): 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.

NEU-QUAT 64

**NEUTRAL
DISINFECTANT - CLEANER - DEODORIZER
CONCENTRATE**

• ONE STEP DOES IS ALL •

EFFECTIVE AT 2 FL OZ /GALLON (1:64) DILUTION

A HOSPITAL-USE AND BROAD SPECTRUM
DISINFECTANT/ANTIMICROBIAL AGENT,
DETERGENT CLEANER, AND DEODORIZER

FOR USE ON HARD NONPOROUS INANIMATE SURFACES
IN/ON INDUSTRIAL, INSTITUTIONAL, COMMERCIAL, RESIDENTIAL,
AND MEDICAL FACILITIES, EQUIPMENT, AND VEHICLES

Virucidal* - Fungicidal - Bactericidal

Pseudomonocidal • Staphylocidal • Salmonellicidal

Controls Mold/Mildew Fungi

(Specific species/agents listed on side panel)

**KILLS HIV-1 (AIDS virus) AND HERPES SIMPLEX TYPE 1 & TYPE 2 VIRUSES
ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY
SOILED WITH BLOOD/BODY FLUIDS.**

ACTIVE INGREDIENTS:

Didecyl dimethyl ammonium chloride 2.43%
n-Alkyl (50% C₁₄, 40% C₁₂, 10% C₁₆)

dimethyl benzyl ammonium chloride 1.62%

INERT INGREDIENTS: 95.95%

TOTAL 100.00%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

See side panel for additional precautionary statements.

EPA REG. NO. 10088-106

EPA EST. NO. 10088-WI-1

ACCEPTED NET CONTENTS:

WITH COMMENTS:

in EPA Letter Dated:

☐ 5 ☐ 6 ☐ 20 ☐ 35 ☐ 55 Gallons

Manufactured By:

DEC 23 2002

Athea Laboratories, Inc.

P.O. Box 240014

Milwaukee, WI 53224

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
a disinfectant for the pesticide,
registered under EPA Reg. No. 10088-106

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 medical devices prior to sterilization or high-level disinfection.

**GENERAL USE DIRECTIONS FOR
CLEANING/DISINFECTING/DEODORIZING:**

Not for use on living humans or animals. Do not use in combination with soap or any other product. Working solution should be freshly prepared, used only once, and then discarded; it may not disinfect properly if reused, diluted, or soiled. Prepare the working solution by diluting 2 fl oz of this concentrate to 1 gallon (16 mL/L) with potable (drinking) water. Remove gross filth and heavy soil deposits from surfaces. Apply the working solution with a mop, sponge, cloth, or by spraying or soaking, making sure surfaces are thoroughly wetted. Except for HIV-1(see below), complete disinfection requires a minimum contact time of 10 minutes at about 20°C (68°F). Rinsing is not necessary unless surfaces are to be coated (waxed, polished, painted, etc.).

AS A MILDEWSTAT:

Apply working solution to surfaces as directed above, making sure they are thoroughly wetted. Allow to air dry. Repeat application weekly, or when growth reappears.

**KILL HIV (AIDS Virus) ON PRE-CLEANED
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 DECONTAMINATING AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

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PERSONAL PROTECTION - Appropriate barrier protection items such as disposable latex or vinyl gloves, gowns, face masks, or eye coverings must be worn during decontamination procedures and when cleaning/handling items soiled with blood/body fluids.

CLEANING PROCEDURE - Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of this product as a disinfectant.

CONTACT TIME - Effective against HIV-1 in 4 minutes at room temperature (20 to 25°C; 68 to 77°F). A 10 minute contact time is required for all other viruses, bacteria, and fungi claimed on this labeling.

DISPOSAL OF INFECTIOUS MATERIALS - Blood/body fluids and other materials removed from or used to clean surfaces/objects should be autoclaved and disposed of according to Federal, State, and local regulations for infectious waste disposal.

FEATURES, CLAIMS, AND USES

A labor-saving one-step concentrated multi-purpose antimicrobial/disinfectant/germicidal detergent/deodorizer/cleaner for use on hard, nonporous, inanimate surfaces. The combination of detergents and emulsifiers quickly cuts through and removes dirt, grease, oils, scum, and grime. Its "neutral" pH allows usage on many materials and surfaces that otherwise could be damaged by more alkaline or acidic products.

Virucidal, bactericidal, fungicidal, and mildewstatic at a 2 fl oz/gallon (16 mL/L; 1:64; 600 ppm active "quat") dilution in hard water (up to 400 ppm hardness calculated as CaCO₃) in the presence of 5% organic soil (blood serum) load when tested by the appropriate AOAC or virucidal qualification method (modified to use hard water and organic soil load).

Virucidal* against: Adenovirus Type 4 • Canine distemper • Feline leukemia • Feline panleukopenia • Feline picornavirus • Herpes simplex Type 1 • Herpes simplex Type 2 • HIV-1 (AIDS virus; Human Immunodeficiency virus Type 1) • Infectious bovine rhinotracheitis • Infectious Bronchitis (Avian IBV) • Influenza A/Hong Kong • Porcine parvovirus • Pseudorabies • Rabies • Rubella (German measles) • Vaccinia.

Effective against the following pathogenic bacteria: Bordetella bronchiseptica • Chlamydia psittaci (Psittacosis strain) • Enterobacter aerogenes • Enterobacter cloacae • Enterococcus faecalis* (Streptococcus faecalis) • Escherichia coli* • Fusobacterium necrophorum • Klebsiella pneumoniae* • Pasteurella multocida • Proteus mirabilis • Proteus vulgaris • Psuedomonas aeruginosa* • Salmonella choleraesuis • Salmonella typhi • Salmonella typhimurium • Serratia marcescens • Shigella flexneri • Shigella sonnei • Staphylococcus aureus* • Staphylococcus epidermidis (antibiotic-resistant) • Streptococcus pyogenes

aureus* • Staphylococcus epidermidis (antibiotic-resistant) • Streptococcus pyogenes.

* Both antibiotic-resistant and regular bacterial strains.

Fungicidal against: Candida albicans and Trichophyton mentagrophytes (agent that causes athlete's foot fungi) in areas such as locker rooms, dressing rooms, shower and bath areas and exercise facilities. Follow disinfection directions.

Mildewstatic: Inhibits the growth of fungi (such as Aspergillus niger) that cause mold/mildew and their odors on hard, nonporous, inanimate surfaces, including walls, floors, and table tops.

FOR USE ON: Most hard nonporous surfaces: glazed ceramic, elastomeric, metallic, and plastic surfaces; including glass, glazed porcelain, rubber, aluminum, copper, iron, stainless steel, steel, ABS, bakelite, enamel, polyester, polyethylene, polypropylene, and vinyl.

RECOMMENDED FOR USE IN/ON: Industrial, Institutional, Commercial, Residential, and Medical Facilities, Equipment, and Vehicles, such as hospitals, nursing homes, schools and colleges, veterinary clinics and animal life science laboratories, pet shops, kennels, breeding and grooming establishments, tack shops, hotels and motels, airports, and households; and on floors and walls.

Vehicle Disinfection Directions: Pre-clean all vehicles including mats, crates, and wheels with high pressure water. Use 2 fl. oz. per gallon of water to treat all vehicles. Leave surfaces wet for 10 minutes.

(OPTIONAL USES AND CLAIMS AND DIRECTIONS)

FEATURES, CLAIMS, AND USES

A HOSPITAL-USE AND BROAD SPECTRUM
DISINFECTANT/ANTIMICROBIAL AGENT,
DETERGENT CLEANER, AND DEODORIZER

ACCEPTED FOR USE ON HARD, NONPOROUS, INANIMATE SURFACES
IN INDUSTRIAL, INSTITUTIONAL, COMMERCIAL, RESIDENTIAL,
AND MEDICAL FACILITIES, EQUIPMENT, AND VEHICLES
with COMMENTS
in EPA Letter Dated:

DEC 23 2002
Virucidal* - Fungicidal - Bactericidal
Pseudomonocidal • Staphylocidal • Salmonellicidal

Under the Federal Insecticide, Fungicide, and Rodenticide Act as
Controls Mold/Mildew Fungi
(specific species/agents listed below.)

registered under EPA Reg. No 10088-106

**KILLS HIV-1 (AIDS virus) AND HERPES SIMPLEX TYPE 1 & TYPE 2 VIRUSES
ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY
SOILED WITH BLOOD/BODY FLUIDS.**

Virucidal* against:

- Adenovirus Type 4
- Canine Distemper
- Canine parvovirus
- Feline leukemia
- Feline panleukopenia
- Feline picornavirus
- Herpes simplex Type 1
- Herpes simplex Type 2
- HIV-1(AIDS virus: Human Immunodeficiency virus Type 1) • Vaccinia
- Infectious bovine rhinotracheitis
- Infectious bronchitis (Avian IBV)
- Influenza A/Hong Kong
- Porcine parvovirus
- Pseudorabies
- Rabies
- Rubella (German measles)

Bactericidal against:

- Bordetella bronchiseptica
- Chlamydia psittaci (Psittacosis strain)
- Enterobacter aerogenes
- Enterobacter cloacae
- Enterococcus faecalis* (Streptococcus faecalis)
- Escherichia coli*
- Fusobacterium necrophorum
- Klebsiella pneumoniae*
- Pasteurella multocida
- Proteus mirabilis
- Proteus vulgaris
- Psuedomonas aeruginosa*
- Salmonella choleraesuis
- Salmonella typhi
- Salmonella typhimurium
- Serratia marcescens
- Shigella flexneri
- Shigella sonnei
- Staphylococcus aureus*
- Staphylococcus epidermidis (antibiotic-resistant)
- Streptococcus pyogenes
- * Both antibiotic-resistant and regular bacterial strains.

Virucidal* against: Adenovirus Type 4 (an adenovirus); Canine distemper (a myxovirus); Canine parvovirus (a parvovirus); Feline leukemia (a retrovirus); Feline panleukopenia (a parvovirus); Feline picornavirus (a calicivirus); Herpes simplex Type 1 (a herpesvirus); Herpes simplex Type 2 (a herpesvirus); HIV-1(AIDS virus; Human Immunodeficiency virus Type 1; a retrovirus that causes "AIDS"); Infectious bovine rhinotracheitis (a herpesvirus); Infectious bronchitis (Avian IBV)(a coronavirus); Influenza A/Hong Kong (an orthomyxovirus); Porcine parvovirus (a parvovirus); Pseudorabies (a herpesvirus); Rabies (a rhabdovirus); Rubella(German measles)(a togavirus); and Vaccinia (a poxvirus).

Effective against the following pathogenic bacteria: Bordetella bronchiseptica, Chlamydia psittaci (Psittacosis strain VR-854), Enterobacter aerogenes, Enterobacter cloacae, Enterococcus faecalis* (Streptococcus faecalis), Escherichia coli*, Fusobacterium necrophorum, Klebsiella pneumoniae*, Pasteurella multocida, Proteus mirabilis, Proteus vulgaris, Psuedomonas aeruginosa*, Salmonella Choleraesuis,

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Salmonella typhi, Salmonella typhimurium, Serratia marcescens, Shigella flexneri, Shigella sonnei, Staphylococcus aureus*, Staphylococcus epidermidis (antibiotic resistant), and Streptococcus pyogenes.

* Both antibiotic-resistant and regular bacterial strains.

RECOMMENDED FOR USE IN/ON: Funeral homes, mortuaries, and morgues; on poultry and turkey farms, equine farms, sheep farms, dairy and beef farms, and hog farms.

For use in meat and poultry plants as a general cleaning agent on all surfaces, or for use with steam or mechanical cleaning devices in all departments. Before use of this compound, food products and packaging materials must be removed from the area or carefully protected. After use, all surfaces in the area must be thoroughly rinsed with potable (drinking) water.

DIRECTIONS FOR USE:

FOR USE IN FUNERAL HOMES; CLEANSING AND SANITIZATION OF BODY SURFACES AND BODY ORIFICES OF HUMAN REMAINS (to cleanse away skin secretions and accompanying malodor, to ensure removal of all soil and blood stains, and to remove and reduce surface contamination): Apply the 2 fl oz/gallon working solution to the surface and body openings, natural or artificial. Bathe the entire body, using a sponge or washcloth. A soft handbrush may be employed on surfaces other than the face. For optimal results, allow a 10 minute contact time. Prepare a fresh solution for application to each remains.

FOR DISINFECTING ANIMAL LIFE SCIENCE LABORATORIES, VETERINARY CLINICS, PET SHOPS, KENNELS, BREEDING & GROOMING ESTABLISHMENTS, AND FARMS.

Remove all animals and feeds from premises, vehicles, crates, and other enclosures to be treated. Remove all litter, droppings, and manure from floors, walls, and surfaces of barns, pens, stalls, chutes, and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances. Thoroughly clean all surfaces with detergent and rinse with water. Saturate all surfaces with the recommended disinfecting solution for at least 10 minutes. Immerse all trailers, 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. After use, ventilate buildings, coops, cars, boats, and other closed spaces. Do not house animals, or employ equipment until treatment has been absorbed or dried. Thoroughly scrub all treated floor racks, mangers, troughs, automatic feeders, fountains, and waterers with detergent, and rinse with potable (drinking) water before reuse.

STORAGE AND DISPOSAL

Containers 1 gallon or less:

Storage and Disposal

Store in original container in areas inaccessible to children and persons unfamiliar with the product. Do not reuse empty container. Discard in the trash.

Containers greater than 1 gallon:

Storage and Disposal

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

Storage: Store in upright, tightly closed original container in a cool, dry, locked area inaccessible to children and persons unfamiliar with the product. Keep away from sources of ignition, heat, degradation, and contamination (including flames, sparks, hot surfaces, sunlight, and other chemicals).

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

Container Disposal: Do not reuse empty container. 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.

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ACCEPTED
with COMMENTS
in EPA Letter Dated:

DEC 23 2002

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 10088-106

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