

42964-31

09/04/2009

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

SEP 4 2009

Ms. Rhonda Schulz
Ecolab, Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Subject: A-456N
EPA Registration No.: 42964-31
Amendment Date: June 2, 2009
EPA Receipt Date: June 5, 2009

Dear Ms. Schulz,

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

Proposed Amendment

Update Container Disposal Statements per PRN 2007-4

Conditions

Revise the label as follows:

- 1) Revise the Environmental Hazards section on page 1 to be in agreement with the DDAC and ADBAC REDs by adding the following statement "This pesticide is toxic to fish and freshwater aquatic invertebrates."
- 2) Revise the 1st statement of the second claim on page 2 must be brought into compliance with PR Notice 2000-5, Mandatory Labeling, by deleting the term, recommended.
- 3) The nomenclature for Herpes Simplex Type I and Type II, Influenza A2/Hong Kong, Rubella, Vaccina, Feline leukemia, Canine distemper, Rabies, Pseudorabies, and Infectious Bronchitis is incomplete on pages 3. You need to indicate that the microorganisms are viruses by stating "Herpes Simplex *Virus* Type I and Type II, Influenza *Virus* A2/Hong Kong, Rubella *Virus*, Vaccina *Virus*, Feline leukemia *Virus*, Canine distemper *Virus*, Rabies *Virus*, Pseudorabies *Virus*, and Infectious Bronchitis *Virus*."

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4) Revise the "Personal Protection" statement under the HIV directions on page 3 by deleting the term, "or", and replacing it with "and." The personal protection items identified in the statement to use when cleaning blood and body fluids is not optional.

5) The "Disposal of Infectious Material" statement under the HIV directions on page 3 must be brought into compliance with PR Notice 2000-5, Mandatory Labeling, on page 3 by deleting the term, should, and stating, "must."

6) Revise the "Veterinary Clinics, Animal Care, and Animal Laboratories" directions on page 3 by adding the statement, "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." This statement must appear after the contact time statement.

7) The Container Rule rescinded PR Notice 83-3 and 84-1 Part II in which Container Disposal statements are no longer separated by container size but by use pattern, such as residential/household, institutional, commercial, or industrial. Therefore, delete the "Storage and Disposal" statements for containers one gallon or less. Revise the phrase, "Containers greater than 1 gallon" to read "Containers for institutional, commercial, and industrial uses."

8) Revise the "Container Disposal" statements for the institutional/industrial/commercial uses to read:

Container Disposal: Nonrefillable container. Do not reuse or refill container. Clean container promptly after emptying.

(Containers 5 gallons or less)

Triple rinse as follows: Fill container 1/4 full with water and recap. Agitate vigorously. Follow Pesticide Disposal instructions for rinsate disposal. Drain for 10 seconds after the flow begins to drip. Repeat procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

(Container greater than 5)

Triple rinse as follows: Fill container 1/4 full with water. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into the application equipment or mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning. If not available, puncture and dispose in a sanitary landfill.

General Comments

A stamped copy of the label accepted with conditions is enclosed. Submit three (3) copies of your final printed label before distributing or selling the product bearing the revised labeling.

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Should you have any questions or comments concerning this letter, please contact Velma Noble at (703) 308-6233.

Sincerely,



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

Enclosure: Stamped Label

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A-456-N

*Neutral Detergent/Disinfectant/Fungicide/
Virucide*/Odor Counteractant For Hospital,
Veterinary and Industrial Use*

ACCEPTED
with COMMENTS
in EPA Letter Dated:

SEP 4 2009

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

42964-31

Active Ingredients:

Didecyl Dimethyl Ammonium Chloride	10.29%
n-Alkyl (50% C ₁₄ , 40% C ₁₂ , 10% C ₁₆)	
Dimethyl Benzyl Ammonium Chloride	6.86%

Inert Ingredients: 82.85%

Total: 100.0%

**KEEP OUT OF REACH OF CHILDREN
DANGER**

FOR INDUSTRIAL USE ONLY

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive: Causes irreversible eye damage and skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses) and protective clothing when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash 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 for treatment advice. Have a 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.

FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026

Have the product container or label with when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

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 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.

PELIGRO: SI NO PUEDE LEER EN INGLES, PREGUNTE A SU SUPERVISOR SOBRE LAS INSTRUCCIONES DE USO APROPIADAS ANTES DE TRABAJAR CON ESTE PRODUCTO.

A-456-N is a neutral pH, "one-step" disinfectant-cleaner and odor counteractant.

A-456-N with its cleaning and odor counteractant abilities is ~~recommended~~ for disinfecting and cleaning floors, walls, and other hard non-porous environmental surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, shelves, racks, carts, refrigerator exteriors, non-food contact surfaces of coolers, glazed tile, linoleum, vinyl, glazed porcelain, plastic (such as polyethylene, polypropylene, polystyrene, polyvinylchloride, polycarbonate and polymethyl methacrylate), metal, glass, or painted, varnished or lacquered surfaces. Will not harm finished floors. Not for use on medical devices or medical equipment surfaces.

Areas of Use: Hospitals, nursing homes, other health care-facilities, schools and colleges, veterinary clinics and animal life science laboratories, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments.

When used as directed, this product will deodorize surfaces in toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors. A potable water rinse is required when used on a food contact surface.

DIRECTIONS FOR USE

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

DISINFECTION: For hospital disinfection against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Salmonella choleraesuis* and cleaning of hard non-porous surfaces use 1/2 ounce per gallon of water (1:256). Apply solution with a wet cloth, mop, brush, scrubber, or by soaking. Allow to remain wet for at least 10 minutes. Remove solution and entrapped soil with a clean, wet mop, cloth or wet vacuum pickup. For heavily soiled areas, a precleaning step is required. Rinsing is not necessary on non-food contact surfaces. Do not use this product to clean or disinfect glassware, dishes or silverware. Prepare a fresh solution at least daily or when solution is visibly dirty.

Effective at 1:256 against the following pathogenic bacteria according to the AOAC Use-Dilution Test modified in the presence of 5% blood serum.

<i>Pseudomonas aeruginosa</i>	<i>Klebsiella pneumoniae</i>	<i>Staphylococcus aureus</i> (antibiotic resistant)
<i>Staphylococcus aureus</i>	<i>Proteus vulgaris</i>	<i>Streptococcus faecalis</i> (antibiotic resistant)
<i>Salmonella choleraesuis</i>	<i>Serratia marcescens</i>	<i>Escherichia coli</i> (antibiotic resistant)
<i>Enterobacter cloacae</i>	<i>Shigella flexneri</i>	<i>Klebsiella pneumoniae</i> (antibiotic resistant)
<i>Streptococcus pyogenes</i>	<i>Shigella sonnei</i>	<i>Staphylococcus epidermidis</i> (antibiotic resistant)
<i>Streptococcus faecalis</i>	<i>Salmonella typhi</i>	<i>Pseudomonas aeruginosa</i> (antibiotic resistant)
<i>Enterobacter aerogenes</i>	<i>Proteus mirabilis</i>	<i>Fusobacterium necrophorum</i>
<i>Salmonella typhimurium</i>	<i>Escherichia coli</i>	<i>Enterococcus faecalis</i> (vancomycin resistant)

FUNGICIDAL: Fungicidal against *Trichophyton mentagrophytes* (the athlete's foot fungus) on surfaces in locker rooms, dressing rooms, shower and bath areas and exercise facilities. Fungicidal against *Trichophyton mentagrophytes* (the athlete's foot fungus) and *Candida albicans* according to the AOAC Fungicidal Test modified in the presence of 5% blood serum at 1:256.

VIRUCIDAL: *Virucidal against HIV-1 (AIDS Virus), HBV (Hepatitis B Virus), HCV (Hepatitis C Virus), Adenovirus type 4, Herpes simplex Type 1 and Type 2, Influenza A2/Hong Kong, Rubella, Vaccinia, Feline picornavirus (Calicivirus), Feline leukemia, Canine distemper, Rabies, Porcine parvovirus, Pseudorabies, and Infectious bronchitis (Avian IBV) according to the Virucidal Qualification Test, modified in the presence of 5% blood serum at 1:256.

KILLS HIV (AIDS VIRUS) AND HBV (HEPATITIS B VIRUS) AND HCV (HEPATITIS C 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). A-456-N is effective as a virucide at 1/2 ounce per gallon of water on hard, non-porous surfaces when used in health care settings where the potential for the transmission of HIV-1 (AIDS virus) or HBV (Hepatitis B Virus) or HCV (Hepatitis C Virus) on inanimate surfaces is likely.

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SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OR HBV OR HCV ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

Personal Protection: When handling items soiled with blood or body fluids, wear personal protection such as disposable latex gloves, gowns, masks and eye coverings to guard against contact with these fluids.

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

Contact Time: HIV-1 is inactivated after a contact time of 4 minutes at room temperature (20-25°C). HBV and HCV are inactivated after a 10 minute contact time. Use a ten minute contact time for all other bacteria, fungi, and viruses claimed (listed on label).

Disposal of Infectious Materials: Blood and other body fluids ~~should~~ be autoclaved or incinerated and disposed of according to local regulations for infectious waste disposal.

For Use in Veterinary Clinics, Animal Care, and Animal Laboratories:

For cleaning and disinfecting the following hard nonporous surfaces: equipment not used for feeding or watering animals, utensils, instruments, cages, kennels, stables, catteries, etc.. Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Thoroughly clean all surfaces with soap or detergent and water and rinse with water. Saturate surfaces with a use-solution of 1/2 ounce of product per gallon of water and allow to remain wet for 10 minutes. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

Containers ~~1~~ gallon or less:

STORAGE & DISPOSAL

Store in original container in areas inaccessible to children and persons unfamiliar with its proper use. Do not reuse container. Wrap container and discard in the trash.

Containers greater than ~~1~~ gallon:

STORAGE & DISPOSAL

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

PESTICIDE STORAGE: Store this product in a cool, dry area, away from direct sunlight and heat.

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 the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL:

(≤ 55-gallons rigid) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying.

(2.5 gal bladder in box) Nonrefillable container. Do not reuse or refill this container. Remove empty bladder from outer corrugated box. Triple rinse bladder (or equivalent). Offer box and bladder for recycling, if available.

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Net Contents:
1 U.S. gal. (3.78 L)
1 L
1.3 L
2 L
2.5 U.S. gal.
5 U.S. gal. (18.9 L)

EPA Reg. No. 42964-31
EPA Est.:1677-IL- 2 (J), 1677-NJ-1 (W), 1677-TX-1 (D), 1677-GA-1 (M), 1677-MN-1 (P), 1677-CA-1 (S),
1677-PR-1 (B), 1677-OH-1 (H), 303-IN-1 (L), 1677-CA-2 (R), 1677-WV-1 (V).
Superscript refers to first letter of date code.

Airkem Professional Products, Division of Ecolab Inc.
370 North Wabasha Street N.
St. Paul, MN 55102