

42964-31

12-16-2009

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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

DEC 16 2009

Theodore D. Head
Product Registration Manager
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102

Subject: A-456-N
EPA Registration No. 42964-31
Notification Date: November 09, 2009
EPA Receipt Date: November 19, 2009

Dear Mr. Head,

This letter acknowledges receipt of your notification, submitted under the provisions of PR Notice 98-10 and FIFRA section 3(c)9.

Proposed Notification

- Adding 2009 H1N1 marketing claims

1. General Comments

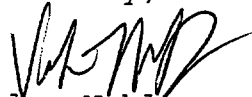
Based on a review of the material submitted, your notification to add 2009 H1N1 marketing claims is acceptable. A copy has been inserted in our records for future reference.

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

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

Sincerely,



Velma Noble

Product Manager (31)

Regulatory Management Branch I

Antimicrobials Division (7510P)



United States
Environmental Protection Agency
Washington, DC 20460

- Registration
- Amendment
- Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 42964-31	2. EPA Product Manager Velma Noble	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
3. Company/Product (Name) A-456-N	PM# 31	
5. Name and Address of Applicant (Include ZIP Code) Ecolab Inc. 370 N. Wabasha Street St. Paul, MN 55102		6. Expedited Review. In accordance with FIFRA Section 3 (c) (3) (b) (i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____
<input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional Page(s) if necessary. (For section I and Section II)

Optional Marketing Claims in accordance with EPA guidance for labeling against Pandemic 2009 H1N1 for EPA Reg. No. 42964-31.

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
	If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Unit Package wgt. No. Per Container	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 gal, 5 gal, 1 L & 2 L	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted if necessary to process this application.)		
Name Theodore D. Head	Title Product Registration Manager	Telephone No. (Include Area Code) (651) 293-2848
Certification I certify that the statements which I have made on this form and all attachments are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>Theodore D. Head</i>	3. Title Product Registration Manager	
3. Typed Name Theodore D. Head	4. Date 11/09/2009	



THEODORE HEAD
 Manager, Product Registration
 Regulatory Affairs
 T 651.293.2848
 F 651.225.3122
 ted.head@ecolab.com

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November 9, 2009

Document Processing Desk (E-SUB)
 Office of Pesticide Programs (7502P)
 U.S. Environmental Protection Agency
 2777 S. Crystal Drive
 Arlington, VA 22202

ATTN: Velma Noble, PM-31

RE: A-456-N, EPA Reg. No. 42964-31

Subject: Optional Marketing Claims in accordance with EPA Guidance for Labeling against Pandemic 2009 H1N1 for EPA Reg. No. 42964-31

Dear Velma:

Ecolab desires to add, via notification, optional marketing claims in accordance with EPA Guidance for Labeling Claims against Pandemic 2009 H1N1.

Please note that no other changes have been made to the label. Enclosed are the following documents:

- EPA Form 8570-1.
- Certification with Respect to Label Integrity.
- Proposed Labeling (5 copies)
- Label CD

If you have any questions please contact me at the above phone, fax or email address.

Sincerely,

Theodore D. Head
 Product Registration Manager
 Regulatory Affairs
 Ecolab Inc.

cc: [illegible]
 cc: [illegible]
 cc: [illegible]
 cc: [illegible]
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 cc: [illegible]


Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
42964-31	11/09/2009	042964-00031.20091109_v01.H1N1.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



 Signature

11-9-09

 Date

Theodore Head

 Name (typed)

Product Registration Manager

 Title

A-456-N

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

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): This product is toxic to fish and freshwater aquatic invertebrates. 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 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 enterica* 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 enterica</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 Virus Type 1 and Type 2, Influenza Virus A2/Hong Kong, Rubella Virus, Vaccinia Virus, Feline picornavirus (Calicivirus), Feline leukemia Virus, Canine distemper Virus, Rabies Virus, Porcine parvovirus, Pseudorabies Virus, and Infectious bronchitis Virus (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.

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 must 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. 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. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

Containers for institutional, commercial and industrial uses.

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:

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

(< 5-gallon rigid) Triple rinse as follows: Fill container ¼ 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.

(> 5--gallons rigid) Triple rinse as follows: Fill container ¼ 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.

(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-TX-1 (D), 1677-GA-1 (M), 1677-MN-1 (P), 1677-CA-1 (S), 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

Optional marketing language:

Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by influenza A virus.

This product is a broad-spectrum hard surface disinfectant that has been shown to be effective against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

This product has demonstrated effectiveness against influenza A virus and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 influenza A virus.

This product has demonstrated effectiveness against (influenza A virus tested and listed on the label) and is expected to inactivate all influenza A viruses including Pandemic 2009 H1N1 (formerly called swine flu).

Kills Pandemic 2009 H1N1 influenza A virus (formerly called swine flu).

Kills Pandemic 2009 H1N1 influenza A virus.