

1677-21

12/30/2009

1098

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



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

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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

DEC 30 2009

Subject: Mikro-Quat
EPA Reg. No. 1677-21
Application Dated: November 25, 2009
Receipt Date: November 30, 2009

Dear Theodore D. Head

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9. is acceptable.

Proposed Amendment

Adding marketing language for the Pandemic H1N1
Removing Establishment Number

Comments

Based on a review of the material submitted, the following comments apply:
This application for notification to add marketing language for the Pandemic H1N1 and removing establishment number is acceptable. A copy has been placed in our records for future reference.

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 Branch1 Antimicrobia
Division (7510P)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

2018



United States
Environmental Protection Agency
 Washington, DC 20460

**Registration
 Amendment
 Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 1677-21	2. EPA Product Manager Sharon Carlisle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
3. Company/Product (Name) Mikro-Quat	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Huntington Professional Products, A Service of Ecolab Inc. 370 N. Wabasha Street St. Paul, MN 55102 <input type="checkbox"/> Check if this is a new address		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 _____

Section - II

Amendment - Explain below. Final printed labels in response to

Resubmission in response to Agency letter "Me Too" Application.

Notification - Explain below. Other - Explain below.

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

Adding optional marketing claims in accordance with EPA guidance for labeling against Pandemic 2009 H1N1 and making another minor editorial change for EPA Reg. No. 1677-21 (Mikro-Quat).

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 If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Package wgt. No. Per Container	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) _____
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* Certification must be submitted

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 1 gal., 5 gal.	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
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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.

2. Signature 	3. Title Product Registration Manager	6. Date Application Received (Stamped)
4. Typed Name Theodore D. Head	5. Date November 25, 2009	

Certification with Respect to Label Integrity

version: 9/11/02

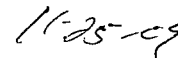
I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
1677-21	11-25-09	001677-00021.20091125_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



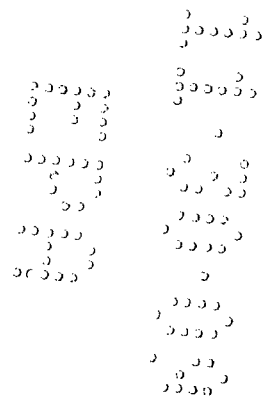
Date

Theodore Head

Name (typed)

Product Registration Manager

Title





4028

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

November 25, 2009

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

ATTN: Sharon Carlisle, PM-31

Subject: Optional Marketing Claims in accordance with EPA Guidance for Labeling against Pandemic 2009 H1N1 for EPA Reg. No. 1677-21 (Mikro-Quat)

Dear Sharon:

Ecolab desires to add, via notification, optional marketing claims in accordance with EPA Guidance for Labeling Claims against Pandemic 2009 H1N1 and make one other minor editorial change.

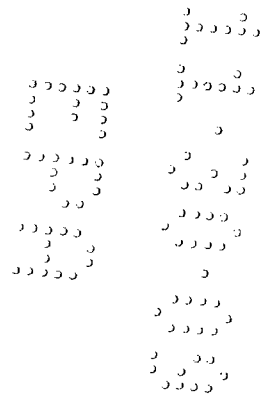
Please note that no other changes have been made to the label. Enclosed are the following documents:

- EPA Form 8750-1.
- 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.



50f8

Mikro-Quat

Detergent•Germicide•Deodorizer

Active Ingredient:

Alkyl (50%C14, 40%C12, 10%C16)
Dimethylbenzyl Ammonium Chloride..... 9.5%
Inert Ingredients*:..... 90.5%
Total:..... 100.0%

*Active as cleaning and buffering agents.

KEEP OUT OF REACH OF CHILDREN
DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE: Causes irreversible eye damage and skin burns. Do not get in eyes or on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses). Wear protective clothing and rubber gloves. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS (only required on containers greater than 5 gallons): Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public 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 sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

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.

CALL A POISON CONTROL CENTER OR PHYSICIAN IMMEDIATELY
FOR EMERGENCY MEDICAL INFORMATION, CALL 1-800-328-0026
OUTSIDE NORTH AMERICA, CALL 1-651-222-5352

(Note to reviewer – The following is optional marketing language)
Detergent - Germicide - Deodorizer - Staphylocidal - Pseudomonacidal - Fungicidal –Cleans, disinfects and deodorizes in one operation - Pleasant Fragrance - Economical to Use
Mikro-Quat has been found effective against Human Immunodeficiency Virus Type 1 (commonly known as the Aids virus) on inanimate surfaces when tested according to EPA virucidal testing requirements.

6008

DIRECTIONS FOR USE

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

Use Mikro-Quat on washable, hard, non-porous surfaces of: glazed ceramic, glazed enamel, glazed porcelain, laminated surfaces, metal, plastic, stainless steel

For disinfection, apply *Mikro-Quat* to walls, floors, sinks, counter tops, hard nonporous surface furnishings and equipment with cloth, mop or hand spray bottle. Wet surfaces thoroughly and allow to remain wet for at least 10 minutes. Preliminary removal of gross soil is required. Prepare fresh solution daily or more often if the solution becomes diluted or soiled.

Use *Mikro-Quat* in hospitals (suitable for conductive floors), nursing homes, food service facilities, schools and animal research facilities.

To Clean and Deodorize

Use 1/3 oz. Mikro-Quat per gallon of water to clean and deodorize surfaces. Apply using a cloth, mop, sponge or sprayer. Wipe or allow to air dry.

Light-Duty Cleaning, and Sanitizing - Non-Food contact Surfaces

Use 1/3 oz. *Mikro-Quat* per gal. of warm or hot water (235 ppm). Allow 1 minute contact time. At this concentration the product is effective in the presence of protein (5% blood serum) against *Escherichia coli* 0157:H7, *Staphylococcus aureus*, and *Enterobacter aerogenes*.

Combination Disinfection and Cleaning

Use 1 oz. *Mikro-Quat* per gal. of water (700 ppm). Allow 10 minutes contact time. Remove solution and entrapped soil with clean wet mop, cloth or wet vacuum pickup.

Mikro-Quat has been found effective against the following bacteria at 1 oz. per gallon in the presence of protein (5% blood serum):

<i>Staphylococcus aureus</i> (ATCC 6538)	<i>Escherichia coli</i> (ATCC 11229)
<i>Salmonella typhi</i> (ATCC 6539)	<i>Staphylococcus aureus</i> HL121 (Methicillin resistant)
<i>Trichophyton mentagrophytes</i> (ATCC 9533)	<i>Vibrio cholerae</i> (ATCC 25873)
<i>Proteus vulgaris</i> (ATCC 13315)	<i>Pseudomonas aeruginosa</i> (ATCC 15442)
<i>Enterococcus faecalis</i> (vancomycin resistant) (ATCC 51299)	
<i>Salmonella enterica</i> (ATCC 10708)	

Virucidal: Disinfects the following viruses on inanimate environmental surfaces at a use dilution of 1:128 (1 oz. per gal. of water). *Mikro-Quat* has been found effective against the following viruses at 1 oz. per gallon in the presence of protein (5% blood serum):

HIV-1 (AIDS virus)	Vaccinia (ATCC VR-119)
Herpes Simplex, type 1 (ATCC VR-733)	Influenza A2/Hong Kong (ATCC VR-544)
Newcastle Disease virus (ATCC VR-108)	
Norovirus (Feline calicivirus surrogate - (ATCC VR-782)	

This product kills HIV 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 the transmission of human Immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 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.

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

CONTACT TIME: 10 minutes.

DISPOSAL OF INFECTIOUS MATERIAL: Blood and other body fluids must be autoclaved and disposed of according to local regulations for infectious waste disposal.

KILLS PATHOGENIC FUNGI (*T. mentagrophytes*), the agent that causes Athlete's foot fungus, on inanimate surfaces such as shower room floors, bath mats, and locker room benches at the use concentration of 1 oz. per gallon of water (700 ppm). Follow the disinfection directions and allow 10 minute contact time.

KILLS MILDEW FUNGI on inanimate surfaces at the use concentration of 1 oz. per gallon of water 700 ppm). Follow the disinfection directions and allow 10 minute contact time.

DO NOT MIX WITH ANYTHING BUT WATER

DILUTION TABLE:

ppm active quaternary	235	700
oz. per gal. water	1/3	1
dilution equivalent	1:400	1:128

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.

STORAGE & DISPOSAL

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

Pesticide Storage: Store in original container in a locked storage area. Store at ambient temperature. Keep container tightly closed when not in use. Do not freeze.

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.

Net Contents:

1 U.S. Gal. (3.78 L)
15 U.S. Gal. (56.7 L)
55 U.S. Gal. (208 L)

Ecolab Inc.
Institutional Division
370 N. Wabasha Street
St. Paul, MN 55102

EPA Reg. No. 1677-21
EPA Est.: 1677-MN-1 (P), 1677-IL-2 (J)
1677-CA-2 (R), 1677-TX-1 (D), 1677-OH-1 (H)
1677-IL-2 (J), ~~1677-PR-1 (B)~~, 1677-CA-1 (S)
1677-NJ-1 (W), 1677-GA-1 (M), 1677-WV-1 (V)
Superscript refers to first letter of date code

8028

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.