



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

May 6, 2020

Heidi Popelka  
Sr. Regulatory Specialist II  
Ecolab, Inc.  
1 Ecolab Place  
St. Paul, MN 55102

Subject: Label Amendment: Emerging Viral Pathogens Claim  
Product Name: Mikro-Quat  
EPA Registration Number: 1677-21  
Application Date: March 19, 2020  
Decision Number: 560908

Dear Ms. Popelka:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), [https://www.epa.gov/sites/production/files/2016-09/documents/emerging\\_viral\\_pathogen\\_program\\_guidance\\_final\\_8\\_19\\_16\\_001\\_0.pdf](https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf), you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
  - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
    - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
      - A. CDC Current Outbreak List for “U.S. Based Outbreaks” ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)),
      - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification ([www.cdc.gov/outbreaks](http://www.cdc.gov/outbreaks)) (also released through the CDC’s Health Alert Network (HAN) notification process)
      - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page ([www.cdc.gov/hai/outbreaks](http://www.cdc.gov/hai/outbreaks))
    - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page ([www.oie.int/wahis\\_2/public/wahid.php/Diseaseinformation/WI](http://www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI)).
      - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroups are large non-enveloped and enveloped.
      - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Calicivirus [Surrogate for Human Norovirus (ATCC VR-782)] is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at [disinfectantslist@epa.gov](mailto:disinfectantslist@epa.gov).

Sincerely,



Steven Snyderman, Acting Product Manager 33  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

Enclosure: stamped label

# Mikro-Quat

Detergent • Germicide • Deodorizer • Sanitizer • One-Step Disinfectant • Cleaner

## Active Ingredient:

Alkyl (50%C<sub>14</sub>, 40%C<sub>12</sub>, 10%C<sub>16</sub>)

Dimethylbenzyl Ammonium Chloride.....9.5%

Inert Ingredients\*.....90.5%

Total:.....100.0%

\*Active as cleaning and buffering agents.

**ACCEPTED**

05/06/2020

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 1677-21

**KEEP OUT OF REACH OF CHILDREN  
DANGER**

(See [back], [side], [other] label for [complete] [additional] [directions for use] [precautionary statements] [and] [first aid])

## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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

**FOR EMERGENCY MEDICAL INFORMATION, CALL 1-800-328-0026**

**OUTSIDE NORTH AMERICA, CALL 1-651-222-5352**

Have the product container or label with you 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.

(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.

(This use not approved in CA - *will be used for claims not currently approved*)

### **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 non-porous 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 (235 ppm) 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 gallon 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 2 oz. *Mikro-Quat* per gallon of water (1400 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 2 oz. per gallon of water (1400 ppm) with a 10 minute contact time 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>Proteus hauseri</i> (ATCC 13315)
<i>Salmonella enterica</i> (ATCC 10708)	<i>Pseudomonas aeruginosa</i> (ATCC 15442)
<i>Enterococcus faecalis</i> (vancomycin resistant) (ATCC 51299)	

**Virucidal\*** *Mikro-Quat* has been found effective against the following viruses at 2 oz. per gallon of deionized (DI) water (1400 ppm) with a 10 minute contact time 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 hard, non-porous 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 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).

(Note to Reviewer: Language in ( ) is considered optional or interchangeable.)

**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** (*Tricophyton mentagrophytes*), the agent that causes Athlete's foot fungus, on hard, non-porous inanimate surfaces such as shower room floors, bath mats, and locker room benches at the use concentration of 2 oz. per gallon of water (1400 ppm). Follow the disinfection directions and allow 10 minute contact time.

**DO NOT MIX WITH ANYTHING BUT WATER  
DILUTION TABLE:**

	<b>Non-Food Contact Sanitizer / Cleaner</b>	<b>Disinfectant</b>
<i>ppm active quaternary</i>	235	1400
<i>oz. per gal. water</i>	1/3	2
<i>dilution equivalent</i>	1:400	1:64

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. In case of spill, flood the area with large quantities of water. Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer.

**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 Handling and Disposal:**

(For containers 5 gallons or less): Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(For containers greater than 5 gallons): Non-refillable container. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. 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. Follow Pesticide Disposal

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instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by puncture and dispose of in a sanitary landfill, or by incineration.

**Net Contents:**

1 U.S. Gal. (3.78 L)

15 U.S. Gal. (56.7 L)

55 U.S. Gal. (208 L)

Ecolab Inc.  
370 N. Wabasha Street  
St. Paul, MN 55102  
(Made in United States of America) (Made in USA)

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

**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 A2/Hong Kong 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.
- Refer to the (MSDS)(SDS) for additional product hazard information

**SECONDARY CONTAINER LABEL**

(Note to reviewer

When this product is diluted in accordance with the directions on this label, the dilution container must bear the following statements: These statements apply to product diluted at  $\leq 1$  oz. / gallon of water. If product is diluted  $> 1$  oz / gallon, the label must bear the concentrate precautionary language.

**MIKRO-QUAT**

(Concentrate Ingredient Statement)

**Active Ingredient:**

Alkyl (50%C14, 40%C12, 10%C16)

Dimethylbenzyl Ammonium Chloride ..... 9.5%

**Inert (Other) Ingredients\*:** ..... 90.5%

**Total:**.....100.0%

\*Active as cleaning and buffering agents.

The product in this container is diluted as directed on the pesticide product label.

(Diluted product in this container is \_\_\_\_\_ oz per gallon solution)

**KEEP OUT OF REACH OF CHILDREN**

When in use dilution, the product is classified as Acute Toxicity Category IV and requires no PPE or precautionary language.

**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.

Follow the directions for use on the pesticide label when applying this product.

(Use solution prepared by end user)

(Not for sale or distribution)

(Do Not Drink)

EPA Reg. No. 1677-21



### Emerging Viral Pathogens

“This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.”

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large, Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label</i>
Enveloped virus	Norovirus (Feline calicivirus surrogate), ATCC VR-782
Large, non-enveloped virus	Norovirus (Feline calicivirus surrogate), ATCC VR-782

Acceptable claim language:

Mikro-Quat has demonstrated effectiveness against viruses similar to (name of emerging virus) on hard, non-porous surfaces. Therefore, Mikro-Quat can be used against (name of emerging virus) when used in accordance with the directions for use against Norovirus (Feline calicivirus surrogate), ATCC VR-782, on hard, non-porous surfaces. Refer to the (CDC or OIE) website at (pathogen-specific website address) for additional information.

(Name of illness/outbreak) is caused by (name of emerging virus.) Mikro-Quat kills similar viruses and therefore can be used against (name of emerging virus) when used in accordance with the directions for use against Norovirus (Feline calicivirus surrogate), ATCC VR-782, on hard, non-porous surfaces. Refer to the (CDC or OIE) website at (website address) for additional information.

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