

1677-209

05-14-2007

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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

Attention: Joy Salverda
Regulatory Specialist

MAY 14 2007

Subject: KX-6178
EPA Reg. No. 1677-209
Amendment Letter Dated September 29, 2006

The following amendment, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable provided the following label revisions are incorporated:

- On page 3, under the **ENTRYWAY FOAM SANITIZING SYSTEMS** section, delete the wording "harmful organisms".
- On page 3, under the **SHOE BATH SANITIZER DIRECTIONS** section, delete the wording "harmful organisms".
- On page 4, under the **SHOE FOAM SANITIZER DIRECTIONS** section, delete the wording "harmful organisms".
- On page 4, in the sections **COMBINATION DISINFECTION** and **FOAM DISINFECTION**, change *Salmonella choleraesuis* to *Salmonella enterica*.
- On page 3, in the sections listed as **SANITIZING NON-FOOD CONTACT SURFACE** and **FOAM SANITIZING NON-FOOD CONTACT SURFACE** (two section listed under this heading, one of which list **Liquid K** in the use directions) and on page 4 under the section **FOAM DISINFECTION**, remove the use site "drains". The Agency is concerned that the product is not effective in the treatment of drains because of accumulating bio-film that may be present when applied. Moreover, no efficacy data has been submitted to support this claim. As a result, targeted pest may not be affected, and hence, the product may not be efficacious to support the use. The Agency is currently developing policy to address this issue and welcomes the company to comment on the matter. However, until this issue is resolved, the use site is not allowed on this registration.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) and section 4(a) when the Agency requires all registrants of similar products to submit such data.

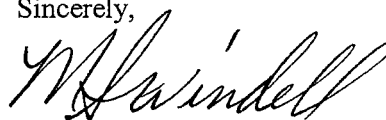
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If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,



Marshall Swindell
Product Manager (33)
Regulatory Management Branch 1
Antimicrobials Division (7510C)

Enclosures:

KX-6178

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SANITIZER AND DISINFECTANT

Acid Liquid Sanitizer for Food Processing Equipment in Dairies, Dairy Farms, Breweries, Wineries, Beverage and Food Processing Plants

Disinfectant for Farms, Livestock Quarters, Poultry Premises, Poultry Hatcheries, Veterinary Clinics, Animal Life Science Laboratories, Animal Care Facilities and Industrial Facilities

Active Ingredients:

Hydrogen Peroxide	7.52%
Peroxyoctanoic Acid	1.00%
Octanoic Acid	2.85%

Other Ingredients:	88.63%
Total:	100.00%

ACCEPTED
with COMMENTS
in EPA Letter Dated
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KEEP OUT OF REACH OF CHILDREN
DANGER

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
1677-209

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE. Causes irreversible eye damage and skin burns. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), coveralls worn over long-sleeved shirt and long pants, socks, chemical resistant gloves, and chemical resistant footwear. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove contaminated clothing and wash clothing before reuse. Prolonged or frequently repeated skin contact may cause an allergic reaction in some individuals.

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 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.

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 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.

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

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

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

PHYSICAL AND CHEMICAL HAZARDS: Strong oxidizing agent. Corrosive. Do not use in concentrated form. Mix only with water according to label instructions. Never bring concentrate in contact with other sanitizers, cleaners or organic substances. This product is not to be used around electrical equipment.

ENVIRONMENTAL HAZARDS (containers 5 gallons or greater): This pesticide is toxic to birds, fish, and 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.

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DIRECTIONS FOR USE

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

SANITIZATION

KX-6178 acid sanitizer is recommended for use on pre-cleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in dairies, dairy farms, breweries, wineries, beverage and food processing plants. This product is effective as a sanitizer when solution is prepared in water of up to 500 ppm hardness as CaCO₃.

NOTE: FOR MECHANICAL OPERATIONS, prepared used solution may not be reused for sanitizing but may be reused for other purposes such as cleaning.

FOR MANUAL OPERATIONS, fresh sanitizing solution should be prepared at least daily or more often if the solution becomes diluted or soiled.

SANITIZING FOOD CONTACT SURFACES

Prior to sanitizing, remove gross food particles, and then wash with a detergent solution, followed by a potable water rinse. Sanitize with a concentration of 1oz **KX-6178** concentrate per 6 to 8 gallons of water (0.1% - 0.13% v/v concentration). At this dilution **KX-6178** is an effective food contact surface sanitizer against the following organisms: *Staphylococcus aureus*, *Escherichia coli*, *Escherichia coli* O157:H7, *Pseudomonas aeruginosa*, *Listeria monocytogenes*, *Salmonella typhimurium*, *Enterobacter sakazakii*, *Campylobacter jejuni* and *Candida albicans*. At the same dilution, **KX-6178** is also effective for sanitization against the common spoilage organisms *Pediococcus damnosus*, *Lactobacillus malefermentans* and *Geotrichum candidum*. Use immersion, coarse spray or circulation techniques as appropriate to the equipment. All surfaces should be exposed to the sanitizing solution for a period of not less than one minute unless a longer time is specified by the governing sanitary code. Drain thoroughly and allow to air dry. Do not rinse.

FOAM SANITIZING FOOD CONTACT SURFACES

KX-6178 is an effective foam sanitizer of pre-cleaned food contact surfaces. Foam sanitize with a concentration of 1 oz **KX-6178** concentrate per 6 to 8 gallons of water (0.1% - 0.13% v/v concentration). At this dilution **KX-6178** is an effective foaming food contact surface sanitizer against the following organisms: *Staphylococcus aureus* and *Escherichia coli*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Salmonella typhimurium*, *Enterobacter sakazakii*. At the same dilution, **KX-6178** is also effective for foam sanitization against the common spoilage organisms *Pediococcus damnosus* and *Lactobacillus malefermentans*. Use an appropriate device to generate foam intended to cover the food contact surfaces. Contact your Ecolab representative for information on a recommended foamer. All surfaces should be exposed to the sanitizing solution for a period of not less than one minute unless a longer time is specified by the governing sanitary code. Drain thoroughly and allow to air dry. Do not rinse.

CONTINUOUS TREATMENT OF CONVEYORS

Wash, rinse and sanitize conveyor equipment. During processing, apply solution containing 1 oz **KX-6178** concentrate per 6 to 8 gallons of water (0.1% - 0.13% v/v concentration) to a conveyor with Mikro Master or other suitable dispensing equipment. At this dilution **KX-6178** is effective against *Staphylococcus aureus*, *Escherichia coli*, *Escherichia coli* O157:H7, *Pseudomonas aeruginosa*, *Listeria monocytogenes*, *Salmonella typhimurium*, *Enterobacter sakazakii*, *Campylobacter jejuni* and *Candida albicans*. At the same dilution **KX-6178** is effective at reducing the common spoilage microorganisms *Pediococcus damnosus*, *Lactobacillus malefermentans* and *Geotrichum candidum*. Controlled volumes of **KX-6178** are applied to return portion of conveyor through nozzles so located as to permit maximum drainage of **KX-6178** from equipment and to prevent puddles on top of belt. During interruptions in operations, coarse spray the processing equipment with **KX-6178** solution at not more than 0.13% v/v concentration. Conveyor equipment must be free of product when applying coarse spray. Conveyor surface should be exposed to the sanitizing solution for a period of not less than one minute.

ACCEPTED
with COMMENTS
in EPA Letter Dated

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16 77-209

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SANITIZING NON-FOOD CONTACT SURFACES

Pre-clean surfaces as directed above. Sanitize non-food contact surfaces such as floors, walls, tables, chairs, benches, ~~troughs~~, troughs, and drip pans with 1 to 5 oz **KX-6178** concentrate per 8 gallons of water (0.1% - 0.5% v/v concentration). At this concentration the product is effective as a non-food contact surface sanitizer against the following organisms: *Staphylococcus aureus*, *Enterobacter aerogenes*, *Listeria monocytogenes*, *Salmonella typhimurium*, *Pseudomonas aeruginosa*, *Enterobacter sakazakii* and *Geotrichum candidum*. All surfaces should be exposed to the sanitizing solution for a period of not less than 5 minutes. Drain thoroughly and allow to air dry. No rinse necessary.

FOAM SANITIZING NON-FOOD CONTACT SURFACES

KX-6178 is an effective foam sanitizer of pre-cleaned non-food contact surfaces, such as boots, floors, walls, ~~troughs~~, and associated equipment. Sanitize with a concentration of 1 to 5 oz **KX-6178** concentrate per 8 gallons of water (0.1% - 0.5% v/v concentration). At this concentration the product is effective as a non-food contact surface sanitizer against *Staphylococcus aureus*, *Enterobacter aerogenes*, *Listeria monocytogenes*, *Salmonella typhimurium*, *Enterobacter sakazakii* and *Campylobacter jejuni*. Use an appropriate device to generate foam intended to cover non-food contact surfaces. Wet surfaces thoroughly. Surfaces should be exposed to the sanitizing foam for a period of not less than 5 minutes. No rinse is necessary. Contact your Ecolab representative for information on a recommended foamer.

FOAM SANITIZING NON-FOOD CONTACT SURFACES

KX-6178 is an effective foam sanitizer of pre-cleaned non-food contact surfaces, such as boots, floors, walls, ~~troughs~~, and associated equipment. To foam sanitize, prepare a solution of 1 to 5 oz **KX-6178** concentrate per 8 gallons of water (0.1% - 0.5% v/v concentration) and 1.4 oz **Liquid K** per 8 gallons (0.13% v/v concentration). **Liquid K** is the only approved foam generator. At this concentration the product is effective as a non-food contact surface sanitizer against *Staphylococcus aureus*, *Enterobacter aerogenes*, *Listeria monocytogenes*, *Salmonella typhimurium*, *Enterobacter sakazakii* and *Campylobacter jejuni*. Use an appropriate device to generate foam intended to cover non-food contact surfaces. Wet surfaces thoroughly. Surfaces should be exposed to the sanitizing foam for a period of not less than 5 minutes. No rinse is necessary. Contact your Ecolab representative for information on a recommended foamer.

ENTRYWAY FOAM SANITIZING SYSTEMS:

To prevent cross contamination of ~~harmful organisms~~ from area to area, set the system to deliver sanitizing solution at 1 oz **KX-6178** per 1 to 8 gallons of water (0.1% - 0.78% v/v).

Alternately, **KX-6178** can be used along with **Liquid K** to apply the foam by setting the system to deliver 1 oz **KX-6178** per 1 to 8 gallons of water (0.1% - 0.78% v/v) and 1.4 oz **Liquid K** per 8 gallons of water (0.13% v/v concentration).

The foam (or spray) should cover the entire path of the doorway. Set the system so that a continuous wet blanket of sanitizer solution is delivered to the floor.

SHOE BATH SANITIZER DIRECTIONS:

To prevent tracking ~~harmful organisms~~ (into animal areas) (and the packaging and storage areas of food plants), shoe baths containing one inch of freshly made solution should be placed at all entrances to buildings and hatcheries. Scrape waterproof work boots (shoes) and place in solution of 1 oz **KX-6178** per 6 to 8 gallons of water (0.1% - 0.13% v/v) for one minute prior to entering area. (If there is a heavy soil load or excessive traffic place work (boots) (shoes) in a use-solution of 1 oz per 1 to 8 gallons of water (0.1 - 0.78% v/v) (or equivalent dilution) for one minute prior to entering area). Change the solution in the bath daily or more often if solution appears diluted or soiled.

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in EPA Letter Dated:

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1677-209

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SHOE FOAM SANITIZER DIRECTIONS:

KX-6178 can be used to prevent tracking ~~harmful organisms~~ into processing, packaging and storage areas of food and beverage plants. Apply a foam layer approximately 0.5 to 2 inches thick made from a solution of 1 oz per 1 to 8 gallons of water (0.1% - 0.78% v/v) at all entrances to buildings, hatcheries, production and packaging rooms by using a foam generating machine or aerator to apply foam layer. Follow the foaming directions as specified by the manufacturer of the foam generator/aerator. Scrape waterproof shoes. Stand and/or walk through foamed area for one minute prior to entering area. Foam area should be washed and replaced daily or when it appears dirty.

DISINFECTION

KX-6178 disinfects as it cleans in one operation. **KX-6178** can be used to disinfect floors, walls and other hard nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, shelves, racks, carts, exterior surfaces of refrigerators and coolers, tile, linoleum, vinyl, glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass. Areas of use include dairies, dairy farms, breweries, wineries, beverage and food processing plants, poultry farms, veterinary facilities, animal care facilities and industrial facilities.

Before use in federally inspected meat and poultry food processing plants and dairies, food products and packaging material must be removed from the room or carefully protected.

COMBINATION DISINFECTION AND CLEANING

KX-6178 is effective as a disinfectant at a concentration of 1 – 2 oz **KX-6178** concentrate per 2 gallons (0.39% - 0.78% v/v concentration) of hard water (500 ppm as CaCO₃), in the presence of 5% blood serum. At this dilution, **KX-6178** is effective against *Staphylococcus aureus*, *Salmonella* ~~choleraesuis~~, *Pseudomonas aeruginosa* and *Candida albicans*. For heavily soiled areas a pre-cleaning step is required. Prepare a disinfecting and cleaning solution by diluting 1 – 2 oz **KX-6178** concentrate per 2 gallons of water (0.39% - 0.78% v/v concentration). Apply use solution with mop, cloth, sponge, brush, scrubber, or coarse spray device or by soaking or foaming so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, and then remove solution and entrapped soil with a clean wet mop, cloth, or wet vacuum pickup. Prepare a fresh solution daily or when it becomes soiled or diluted.

enteric

FOAM DISINFECTION

KX-6178 is an effective foam disinfectant and cleaner on hard, non-porous surfaces, such as boots, floors, walls, drains, and associated equipment. For this application, prepare a solution of 1 – 2 oz **KX-6178** concentrate per 2 gallons of water (0.39% - 0.78% v/v concentration). Apply solution as a foam using recommended equipment. Wet surfaces thoroughly. At this concentration, the product is effective against the following: *Staphylococcus aureus*, *Salmonella* ~~choleraesuis~~, *Pseudomonas aeruginosa*. Surfaces should be exposed to the disinfecting foam for a period of not less than 10 minutes. No rinse is necessary. Contact your Ecolab representative for information on a recommended foamer.

enteric

VIRUCIDAL

KX-6178 is an effective virucide at a concentration of 1 - 2 oz per 2 gallons (0.39%-0.78% v/v concentration) of hard water (500 ppm as CaCO₃), in the presence of 5% blood serum. At this dilution, **KX-6178** is effective against Influenza A (H1N1), Influenza A (H3N2), Influenza B, Reovirus, Influenza A, Norovirus, Feline calicivirus and Avian Influenza when used at 20°C with a 10 minute contact time. Apply as directed under Disinfection.

DIRECTIONS FOR FOGGING

To sanitize hard surfaces as an adjunct to acceptable manual cleaning and disinfecting of room surfaces: Prior to fogging, food products and packaging materials must be removed from the room or carefully protected. Fog desired areas using one quart of a 0.39% - 0.78% v/v (3900 – 7800 ppm product) **KX-6178** solution (1 - 2 oz. per 2 gallons of water) per 1000 cu. ft. of room volume. Vacate the area of all personnel during fogging and until the hydrogen peroxide air concentration is below 0.5 ppm. Allow surfaces to drain thoroughly before operations are resumed. Solutions above 0.5% may be corrosive and are not to be used on all surfaces. Test solutions on surfaces prior to use. All hard surfaces and food contact surfaces treated with the fog must be rinsed thoroughly with a potable water rinse.

ACCEPTED WITH COMMENTS
MAY 14 2007

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, Registration under such Reg. No 1677-289

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STORAGE & DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

PESTICIDE STORAGE: Product should be kept cool and in a vented container to avoid any explosion hazard.

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:

(1 gallon) Do not reuse empty containers. Wrap container and put in trash.

(4, 15, 30, 50 gallons plastic) 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.

(2.5 gal bladder in box) Remove empty bladder from outer corrugated box. Triple rinse bladder (or equivalent). Offer box and bladder for recycling or dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

(Totes) Verify that the tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

FOR COMMERCIAL USE ONLY
STRONG OXIDIZING AGENTEPA Reg. No. 1677-209
EPA Est. 1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2(R),
1677-TX-1(D), 1677-OH-1(H), 1677-IL-1(J), 1677-GA-1(M),
1677-PR-1(B), 1677-CA-1(S), 1677-WV-1(V)
Superscript refers to first letter of date code

Net Contents:	1 U.S. Gal. (3.78 L)
	5 U.S. Gals. (18.9 L)
	15 U.S. Gals. (56.8 L)
	50 U.S. Gals. (189 L)
	300 U.S. Gals. (tote)

Ecolab Inc.,
370 N. Wabasha Street
St. Paul, MN 55102ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAY 14 2007Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, the pesticide is
registered under EPA Reg. No.

1677-209