

1677-158

10/11/2001

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 11 2001

Brian Brosdahl  
Ecolab Inc.  
370 N. Wabasha Street  
St. Paul, MN 55102-1390

Subject: **KX-6049**  
**EPA File Symbol 1677-158**  
**Your Re-Submissions Dated 2/10/2001, 8/21/2001; Original Amendment**  
**Dated 8/11/2000**

The re-submissions referred to above, submitted in connection with registration under Section 3(c)(7)(A) the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to provide revised labeling and a revised product specific data matrix, is acceptable with the following requirements.

1. Submit/cite all data required for registration and/or reregistration of your product under FIFRA section 3 (c) (5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. We considered your request to change the final sterile water rinse for bottled water sanitization to the FDA regulatory wording, "...disinfected water rinse free of pathogenic bacteria". We will allow this change. Submit five copies of a revised final printed label incorporating this change. If you want this revised label stamped, it must be submitted by amendment. Otherwise, it can be submitted by notification.

If these 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 constitutes acceptance of these conditions.

A stamped copy of the approved label and efficacy review are enclosed for your records.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Swindell,  
Acting Product Manager Team 33,  
Regulatory Management Branch I  
Antimicrobials Division (7510C)

## CONCURRENCES

SYMBOL							
SURNAME							
DATE							

276

# KX-6049

ACID LIQUID SANITIZER FOR FOOD PROCESSING EQUIPMENT  
in Dairies, Dairy Farms, Breweries, Wineries, Beverage and Food Processing Plants

## DISINFECTANT

Hospitals, Health Care Facilities, Animal Care Facilities, Veterinary Facilities, Farms, Livestock Quarters,  
Poultry Premises, and Poultry Hatcheries

STERILANT FOR ASEPTIC MANUFACTURING AND PACKAGING EQUIPMENT

DISINFECTANT FOR THE PHARMACEUTICAL AND COSMETIC INDUSTRY

### Active Ingredients:

Hydrogen Peroxide .....	6.9%
Peroxyacetic Acid .....	4.4%
Octanoic Acid .....	3.3%

Inert Ingredients ..... 85.4%

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

OCT 11 2001

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

1677-158

## KEEP OUT OF REACH OF CHILDREN DANGER

### PRECAUTIONARY STATEMENTS - HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CORROSIVE:** Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing and rubber gloves. Wash thoroughly after handling with soap and water, and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse. When spraying or fogging, wear a mask or pesticide respirator jointly approved by Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.

### 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 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.

**IF SWALLOWED:** Call a poison control center or doctor immediately 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 the poison control center or doctor. Do not anything by mouth to an unconscious person.

**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.

**ENVIRONMENTAL HAZARDS:** (containers 5 gal. 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 the 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.

**DIRECTIONS FOR USE**

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

**SANITIZATION**

**KX-6049** is recommended for use on pre-cleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in dairies, 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  $\text{CaCO}_3$ .

OCT 11 2001  
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 Fungicide, and Rodenticide Act as  
 amended, for the pesticide,  
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**SANITIZING FOOD CONTACT SURFACES**

Prior to sanitizing, remove gross food particles, then wash with a detergent solution, followed by a potable water rinse. Sanitize with a concentration of 1 to 2 ounces **KX-6049** per 6 gallons of water (0.13 - 0.26% v/v concentration). At this dilution **KX-6049** is effective against *Staphylococcus aureus*, *Escherichia coli*, *Escherichia coli* 0157:H7, *Listeria monocytogenes*, *Salmonella typhimurium* (milk isolate), *Pseudomonas aeruginosa*, and *Vibrio cholerae* as well as beverage spoilage organism *Lactobacillus malefermentans*. 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.

**SANITIZING EATING, DRINKING, AND FOOD PREP UTENSILS**

1. Remove gross food particles by a prescrape, preflush and, when necessary, a presoak treatment.
2. Wash with detergent.
3. Rinse with clean water.
4. Sanitize in a solution of 1 to 2 ounces **KX-6049** per 6 gallons of water (0.13 - 0.26% v/v concentration). Immerse all utensils for at least 1 minute or contact time specified by governing sanitary code.
5. Drain and air dry.

**ELEVATED TEMPERATURE SANITIZING**

At a temperature of 120 F. **KX-6049** can be used as a food contact sanitizer at 1 oz. per 14 gallons water (0.055% v/v concentration). At this concentration **KX-6049** is effective against *Staphylococcus aureus* and *Escherichia coli*. All surfaces should be exposed to the sanitizing solution for a period of not less than one minute, unless otherwise specified by governing sanitary code. Drain thoroughly. Do not rinse.

**SANITIZING TABLEWARE**

For sanitizing tableware in low-temperature (minimum 120 F) warewashing machines, inject **KX-6049** into the final rinse water at a concentration of 0.055% v/v (1 oz. per 14 gallons of water) at 120 deg F. Allow 1 minute contact. Air dry.

To insure that the **KX-6049** concentration does not fall below 0.055%, periodically test the rinse solution with a suitable test kit and adjust the dispensing rate accordingly. Consult your local Ecolab Specialist for technical assistance and further information on sanitizing tableware in warewashing machines.

**FINAL SANITIZING BOTTLE RINSE**

**KX-6049** may be used as a final sanitizing rinse for returnable and non-returnable bottles (e.g. glass or PET) at a 0.13% dilution (1 oz to 6 gallons). At this dilution **KX-6049** is effective against *Staphylococcus aureus*, *Escherichia coli*, *Escherichia coli* 0157:H7, *Listeria monocytogenes*, *Salmonella typhimurium*, *Pseudomonas aeruginosa*, *Vibrio cholerae*, and *Lactobacillus malefermentans*. All surfaces should be exposed to the sanitizing solution for a period of not less than 1 minute. Drain thoroughly. No rinse necessary.

NOTE: FOR MECHANICAL OPERATIONS prepared use solutions may not be reused for sanitizing but may be reused for other purposes such as cleaning.  
 FOR MANUAL OPERATIONS fresh sanitizing solutions should be prepared at least daily or more often if the solution becomes diluted or soiled.

**CONTINUOUS TREATMENT OF CONVEYORS FOR MEAT AND POULTRY, CHEESE OR FRUITS AND VEGETABLES**

Wash, rinse and sanitize conveyor equipment. During processing, apply **KX-6049** at a 0.26% v/v (2 oz per 6 gallons water) concentration to conveyor with Mikro Master or other suitable feeding equipment. Controlled volumes of sanitizer are applied to return portion of conveyor through nozzles so located as to permit maximum drainage of sanitizer from equipment and to prevent puddles on top of belt. During interruptions in operations, coarse spray equipment, peelers, collators, slicers and saws with Mikro Master dispensed **KX-6049** solution of 0.26% v/v concentration. Conveyor equipment must be free of product when applying this coarse spray.

KX-6049 label

August 21, 2001

### SANITIZING NON-FOOD CONTACT SURFACES

Preclean surfaces as directed above. Sanitize non-food contact surfaces such as floors, walls, tables, chairs, benches, drains, troughs, drip pans with 1 oz **KX-6049** per 8 gal water (0.1% v/v concentration). At this concentration the product is effective against *Staphylococcus aureus*, *Enterobacter aerogenes*, *Escherichia coli* 0157:H7, *Listeria monocytogenes*, *Salmonella typhimurium* (milk isolate), *Pseudomonas aeruginosa* in 500 ppm hard water. The product is also effective against beverage spoilage organisms: *Aspergillus niger*, *Saccharomyces cerevisiae*, *Pediococcus damnosus* and *Lactobacillus malefermentans*. 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-6049** is an effective foam sanitizer of precleaned non-food contact surfaces, such as boots, floors, walls, and drains, and equipment surfaces. For this application, prepare a solution of 0.13% v/v (1 oz. per 6 gallons water) **KX-6049** and 0.13% v/v (1 oz. per 6 gallons water) **Liquid K**. For example, in six gallons of water, add 1 ounce of **KX-6049** and 1 ounce of **Liquid K**. Apply solution as a foam using recommended equipment. Wet surfaces thoroughly. At this concentration, the product is effective against *Staphylococcus aureus*, *Enterobacter aerogenes*, and *Listeria monocytogenes*. 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 **Liquid K** and a recommended foamer.

### 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 per 1000 cu. ft. of room area with a 0.2% to 1.3 % **KX-6049** solution (3 oz. to 14 oz. per 8 gallons of water). 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. Rinse food contact surfaces prior to start-up with an approved food contact surface sanitizer.

### SANITIZING NON-FOOD CONTACT PACKAGING EQUIPMENT

Prior to use of this product, remove gross soil particles from surfaces. Wash with a recommended detergent solution, rinse thoroughly with potable water. For sanitization against *Staphylococcus aureus*, *Enterobacter aerogenes*, *Escherichia coli* 0157:H7, *Listeria monocytogenes*, *Salmonella typhimurium* (milk isolate), *Pseudomonas aeruginosa* as well as beverage spoilage organisms, *Aspergillus niger*, *Pediococcus damnosus*, *Lactobacillus malefermentans* and *Saccharomyces cerevisiae*, apply 0.1 - 0.5% (1 to 5 oz. per 8 gallons of water) of **KX-6049** to surfaces at a temperature of 25 to 45 deg C and allow to remain wet for at least 5 minutes. Allow surfaces to drain thoroughly before operations are resumed. Drainage may be followed by a potable or sterile water rinse.

### SANITIZE PRECLEANED OR NEW RETURNABLE OR NON-RETURNABLE BOTTLED WATER CONTAINERS

To sanitize precleaned or new returnable or non-returnable containers for bottled water processing, apply **KX-6049** at a concentration of 0.75 to 2.2% (9 to 26 oz. per 10 gallons of water) at a temperature of 40 to 60 deg. C for at least 7 seconds. At these conditions, **KX-6049** is effective against *Staphylococcus aureus*, *Escherichia coli*, *Salmonella typhi*, *Pediococcus damnosus*, *Lactobacillus malefermentans*, *Saccharomyces cerevisiae* and *Aspergillus niger*. After thorough draining, rinse interior container surfaces with a sterile water rinse.

### ANTIMICROBIAL TREATMENT OF WATER FILTERS

To reduce the number of beverage spoilage organisms, *Pediococcus damnosus*, *Lactobacillus malefermentans*, *Saccharomyces cerevisiae* and *Aspergillus niger*, apply **KX-6049** as a 0.75 to 2.2% (9 to 26 oz. per 10 gallons of water) solution at 25 to 45 deg C for a minimum contact time of 5 minutes. After thorough draining, rinse filters with sterile water.

### ANTIMICROBIAL RINSE OF PRECLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS WITH THE ADDITION OF SURFACTANT

To reduce the number of beverage spoilage organisms, *Pediococcus damnosus*, *Lactobacillus malefermentans*, *Saccharomyces cerevisiae*, and *Aspergillus niger*, add a 0.75 to 2.2% (9 to 26 oz. per 10 gallons of water) solution of **KX-6049** to a pre-mixed concentration of up to 0.5% (2 oz per 3 gallons) of (name of product/surfactant) solution. Apply at a temperature of 40 to 60 deg C with a contact time of at least 7 seconds. After thorough draining, rinse interior container surfaces with sterile. Contact Ecolab for a list of acceptable surfactants.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

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**DISINFECTION**

**KX-6049** disinfects as it cleans in one operation. **KX-6049** can be used to disinfect floors, walls and other hard, nonporous surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, bed frames, shelves, racks, carts, refrigerators, coolers, tile, linoleum, vinyl, asphalt, porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass.

Areas of Use: In Hospitals, use **KX-6049** for Surgical and Obstetrical Suites; Housekeeping Services; Physical Therapy Departments; Nursing Services; Autopsy Facilities. Also, use **KX-6049** in nursing homes, other health-care facilities, schools, colleges, veterinary clinics, animal life science laboratories, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments. Not for use on food preparation surfaces, medical devices or medical equipment surfaces.

**COMBINATION DISINFECTION AND CLEANING**

**KX-6049** is effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa* at 0.2% (1 oz/4 gl) in hard water (500 ppm as  $\text{CaCO}_3$ ), 5% blood serum and dried soap film residue on hard nonporous surfaces. For heavily soiled areas a precleaning step is required. Apply solution with mop, cloth, sponge, brush, scrubber, or coarse spray device or by soaking so as to wet all surfaces thoroughly. Allow to remain wet for 10 minutes, 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.

**VIRUCIDAL**

At 0.2% (1 oz/4 gl) **KX-6049** is effective against Influenza B, Influenza A(H3N2), Influenza A (H1N1), Influenza A (H10N7) and Reovirus on hard inanimate surfaces when used at 20 deg C with a 10 minute contact time in the presence of 500 ppm hard water and organic soil. Apply as directed under disinfection.

**FUNGICIDAL**

**KX-6049** can be used on hard nonporous inanimate surfaces such as shower room floors, locker room benches, shower stalls and bath mats. At 0.2% (1oz/4gl) the product is effective against *Trichophyton mentagrophytes* (Athletes Foot Fungi) and *Candida albicans* (pathogenic yeast) in the presence of protein (5% blood serum) and soap scum in 500 ppm hard water with a 10 minute contact time. Apply as directed under disinfection.

**STERILIZATION OF MANUFACTURING, FILLING, AND PACKAGING EQUIPMENT IN ASEPTIC PROCESSES**

Prior to use of this product, remove gross soil particles from processing surfaces, then wash with a recommended detergent solution, followed by a thorough potable water rinse. Prepare a 5% sterilizing solution of **KX-6049**. Circulate, coarse spray, or flood the sterilizing solution as appropriate to the equipment. All surfaces should be exposed to the sterilizing solution for 30 minutes. This product is effective against *Clostridium sporogenes* and *Bacillus subtilis* at 5% (25 oz/4 gl) in 100 ppm hard water and 5% organic load at 20 deg C.

Rinse surfaces completely with either a sterile water or potable water rinse. For food-contact surfaces, follow with a sanitizing solution of **KX-6049**. Allow surfaces to drain thoroughly prior to any food product contact.

This product is not for use as a sterilant on medical devices.

**DISINFECTING PHARMACEUTICAL AND COSMETIC SURFACES**

**KX-6049** is recommended for use on hard, non-porous, environmental surfaces such as floors, walls and processing equipment in pharmaceutical and cosmetic processing facilities.

**KX-6049** is effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa* at 0.2% (1 oz/4 gl) in hard water (500 ppm as  $\text{CaCO}_3$ ), 5% blood serum and dried soap film residue. For heavily soiled areas a precleaning step is required. Rinse all surfaces thoroughly with the disinfecting solution and maintain a contact time of at least 10 minutes. Product contact surfaces must be rinsed with sterile water.

**NOTE:** This product in its use solutions is compatible with stainless steel and aluminum surfaces. This product is intended to be used on any other surface. It is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

ACCEPTED  
With COMMENTS

Letter Dated:

OCT 11 2001

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1677-158

August 21, 2001

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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:** 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.

(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 AGENT**

EPA Reg. No. 1677-129

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-NJ-1(W), 1677-WV-1(V)

Superscript refers to first letter of date code

Ecolab Food and Beverage Division  
Ecolab Inc., 370 N. Wabasha Street  
St. Paul, MN 55102U.S. Patent No. 5200189 and 5314687  
Other Patents Pending

Net Contents:	1 U.S. Gal. (3.78 L)
	4 U.S. Gals. (15.1 L)
	2.5 U.S. Gals.
	15 U.S. Gals. (56.8 L)
	30 U.S. Gals. (113.5 L)
	50 U.S. Gals. (189 L)
	300 U.S. Gals. (tote)

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