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1677-158

8/20/99

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AUG 20 1999

Ann M. Oxford
Ecolab Inc.
370 N. Wabasha Street
St. Paul, MN 55102-1390

Subject: **KX-6049**
EPA File Symbol 1677-158
Your Amendment Dated 5/24/99
Your Letter Dated 5/25/99 With The Chemical Composition of "Liquid K"

The Amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended,

- to add directions for use as a disinfectant in the pharmaceutical and cosmetic industries,
- to revise both the "Precautionary Statements" and the "Statement of Practical Treatment",
- to delete "Agriculture or..." from, "For Agriculture or Commercial Use Only",
- to add the product descriptor, "Disinfectant for Pharmaceutical and Cosmetic Industries",
- to incorporate the label revisions required in the EPA letter dated 1/28/98,


is acceptable provided that you make the following label change before you release the product for shipment bearing the amended labeling.

In the "Precautionary Statements" section, change the last sentence to read, **"When spraying or fogging, wear a mask or pesticide respirator jointly approved by the Mine Safety and Health Administration and the National Institute for Occupational Safety and Health".**

Please note that we have also received your letter dated 5/25/99 which included the chemical composition of "Liquid K". The "Liquid K" product is used for foam applications of "KX-6049", and its composition was required by the EPA letter dated 1/28/98. This requirement is now satisfied. A stamped copy of the label is attached 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)

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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:

AUG 20 1999

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. Wear a mask or pesticide respirator jointly approved by Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention.

IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention.

IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol. **CALL A POISON CONTROL CENTER OR PHYSICIAN IMMEDIATELY.**

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: 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.

FOR COMMERCIAL USE ONLY
STRONG OXIDIZING AGENT

EPA Reg. No. 1677-158
EPA Est. 60156-IL-1

Ecolab Food & Beverage Division
Ecolab Inc. 370 N. Wabasha St.
St. Paul, MN 55102

Net Contents: 50 U.S. Gals. (189 L) 4 U.S. Gals. (15.1 L) 300 U.S. Gals. (Totes)

KX-6049 label

AUG 20 1999

May 24, 1999

U.S. Patent No. 5200189 and 5314687
Other Patents Pending

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
1677-158

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 CaCO_3 .

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 organisms such as *Aspergillus niger*, *Saccharomyces cerevisiae*, *Pediococcus damnosus* and *Lactobacillus buchneri*. 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 otherwise specified by governing sanitary code. Drain thoroughly. Do not rinse.

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 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.

SANITIZING TABLEWARE

For sanitizing tableware in low-temperature 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).

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 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.

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 such as *Aspergillus niger*, *Saccharomyces cerevisiae*, *Pediococcus damnosus* and *Lactobacillus buchneri*. 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 surfaces, such as boots, floors, walls, and drains, as well as non-food contact equipment surfaces. For this application, prepare a solution containing 1 oz per 6 gallons water KX-6049 and 1 oz per 6 gallons water Liquid K, and apply as a foam. 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.

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. 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.

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 such as *Aspergillus niger*, *Pediococcus damnosus*, *Lactobacillus buchneri* 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.

ANTIMICROBIAL RINSE OF PRECLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS

To reduce the number of beverage spoilage organisms, such as *Pediococcus damnosus*, *Lactobacillus buchneri*, *Saccharomyces cerevisiae* and *Aspergillus niger* 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. After thorough draining, rinse interior container surfaces with sterile or potable water.

ANTIMICROBIAL TREATMENT OF WATER FILTERS

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

ANTIMICROBIAL RINSE OF PRECLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS WITH THE ADDITION OF SURFACTANT (NAMES)

To reduce the number of beverage spoilage organisms, such as *Pediococcus damnosus*, *Lactobacillus buchneri*, *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 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 or potable water.

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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 environmental 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.

Use KX-6049 in hospitals, 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.

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 CaCO₃), 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 CaCO₃), 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. If 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.

STORAGE & DISPOSAL

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

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

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KX-6049 label

May 24, 1999

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.

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