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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 15 1996

Ecolab Inc.
Ecolab Center
St. Paul, MN 55102

Attn.: Ann M. Oxford

Subject: Oxonia Active
EPA Registration No. 1677-129
Submission Dated July 31, 1995

The amendment referred to above, submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), is acceptable provided that you comply with the items listed below. This amendment was submitted to add directions for elevated temperature sanitizing, to add foam sanitizing of non-food contact surfaces, and to revise the food contact surface sanitizing temperature range.

1. Submit/cite all data required for registration/-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. Revise your proposed labeling in accordance with the following instructions:

   a. On page 2, under the heading "SANITIZING TABLEWARE" change "...0.1% - 0.28% v/v (1 to 2.8 oz. per gallon of water)" to read "...0.2% -0.28% v/v (2 to 2.8 oz. per gallon of water."

   b. On page 3, under the heading "FOAM SANITIZING NON-FOOD CONTACT SURFACES" change "...30 seconds..." to read "...5 minutes...".

3. Submit five (5) copies of your final printed labeling before you release the product for shipment.

CONCURRENCES								
SYMBOL								
SURNAME								
DATE								

If these conditions are not complied with, the reg ration 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 label is enclosed for your records.

Sincerely yours,

Marion Johnson
Product Manager 31
Antimicrobial Programs Branch
Registration Division (7505C)

OXONIA ACTIVE

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

ACID LIQUID SANITIZER FOR SANITIZING TABLEWARE

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

Active Ingredients:

Hydrogen Peroxide	27.5%
Peroxyacetic Acid	5.8%
Inert Ingredients	66.7%

ACCEPTED
with COMMENTS
In EPA Letter Dated
MAR 15 1996
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended for the pesticide registered under EPA Reg. No. 1677-129

FOR AGRICULTURE OR COMMERCIAL USE ONLY
STRONG OXIDIZING AGENT

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
DANGER: CORROSIVE: Causes severe eye damage and skin burns. Harmful or fatal if swallowed. Do not get in eyes, on skin or on clothing. Wear chemical goggles, rubber gloves and protective clothing when handling this product. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

STATEMENT OF PRACTICAL TREATMENT
IF IN EYES: Flush immediately with cool water. Remove contact lenses. Continue flushing for 15 minutes, holding eyelids apart. Get prompt medical attention.
IF ON SKIN: Immediately wash with plenty of soap and water. Get medical attention.
IF SWALLOWED: Drink promptly large quantities of water. Avoid alcohol. DO NOT induce vomiting. Never give anything by mouth to an unconscious person.
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 public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage plant authority. For guidance contact your State Water Board or Regional Office of the U.S. Environmental Protection Agency.

EPA Reg. No. 1677-129 EPA Est. 1677-MN-1 (P), 60156-IL-1 (SI)
Superscript refers to first letter of date code

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

Klenzade, Division of Ecolab Inc.
Ecolab Center
St. Paul, MN 55102

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

SANITIZATION

Oxonia Active acid sanitizer 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 1.4 ounces **Oxonia Active** concentrate per 4 gallons of water (0.20 - 0.28% v/v concentration). At this dilution **Oxonia Active** is effective against *Staphylococcus aureus, Escherichia coli, Listeria monocytogenes, Salmonella typhimurium, Pseudomonas aeruginosa, Saccharomyces cerevisiae* and *Vibrio cholerae*. Also effective against organisms found in the brewing industry such as *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 two minutes unless otherwise specified by 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 a recommended detergent.
3. Rinse with clean water.
4. Sanitize in a solution of 1 to 1.4 oz **Oxonia Active** to 4 gallon of water. Immerse all utensils for at least 1 minute or contact time specified by governing sanitary code.
5. Drain and air dry.

ELEVATED TEMPERATURE SANITIZING
For sanitization of equipment in food processing plants, restaurants, etc., clean and rinse equipment thoroughly. At a temperature of 120 deg F, **Oxonia Active** is an effective sanitizer for food contact surfaces at a concentration of 0.1% to 0.28% v/v (1 to 2.8 oz. **Oxonia Active** to 8 gallons water) against *Staphylococcus aureus* and *Escherichia coli*. All surfaces should be exposed to the sanitizing solution for a period of not less than 1 minute. Allow equipment to drain thoroughly.

SANITIZING TABLEWARE
For sanitizing tableware in low-temperature warewashing machines, inject **Oxonia Active** into the final rinse water at a concentration of 0.1 - 0.28% v/v (1 to 2.8 oz. per 8 gallons of water). Do not exceed 0.28% v/v. Air dry.

To insure that the **Oxonia Active** sanitizer concentration does not fall below 0.1%, 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
Oxonia Active may be used as a final sanitizing rinse for returnable and non-returnable bottles at a 0.2% dilution (1 oz to 4 gallons).

NOTE: FOR MECHANICAL OPERATIONS prepared use solution 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.

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 **Oxonia Active** per 16 gl water. At this concentration the product is effective against *Staphylococcus aureus, Enterobacter aerogenes, Escherichia coli, Listeria monocytogenes, Salmonella typhimurium, Pseudomonas aeruginosa,* and *Saccharomyces cerevisiae.* Also effective against organisms found in the brewing industry such as *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

Oxonia Active is highly effective for foam sanitizing of precleaned surfaces, such as boots, floors, walls, and drains, as well as not-food contact equipment surfaces. For this application, prepare a solution containing 0.2% v/v (1 oz per 4 gallons water **Oxonia Active** and 0.13% v/v (1 oz per 6 gallons water) Liquid K, and apply as a foam. Surfaces should be exposed to the sanitizing foam for a period of not less than [redacted] 5 minutes. No rinse is necessary.

DIRECTIONS FOR FOGGING: To sanitize hard room surfaces as an ajunct 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 0.30% **Oxonia Active** solution. Vacate the area of all personnel during fogging and for a minimum of 2 hours after fogging. Allow surfaces to drain thoroughly before operations are resumed.

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Fungicide and Rodenticide Act
as amended, for the registered
[illegible]
1677-129

DISINFECTION

Oxonia Active disinfects as it cleans in one operation. **Oxonia Active** 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 **Oxonia Active** for Surgical and Obstetrical Suites; Housekeeping Services; Physical Therapy Departments; Nursing Services; Autopsy Facilities. Also, use Oxonia Active 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.

COMBINATION DISINFECTION AND CLEANING

Oxonia Active is effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa* and *Histoplasma capsulatum** at 0.3% in hard water (500 ppm as $CaCO_3$), 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.

*Not tested in the presence of soap film residue.

TUBERCULOCIDAL

Oxonia Active passes the rigid requirements as a tuberculocide at 0.3% in the presence of 5% blood serum, 500 ppm hard water and residual soap scum on porous and nonporous surfaces at 20 deg C. Remove heavy soil or gross filth prior to disinfection. Allow surfaces to remain wet for 10 minutes, then remove solution with a clean wet mop, cloth, or wet vacuum pickup.

VIRUCIDAL

At 0.3% **Oxonia Active** is effective against Influenza B/Taiwan/2/62, Influenza A(H3N2) and Influenza A (H1N1) 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.

Not to be used on critical or semicritical items as a sterilant or as a high level disinfectant.

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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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OXONIA ACTIVE is designed for use in animal hospitals, animal laboratories, kennels, pet shops, zoos, pet animal quarters, poultry premises, poultry hatcheries, and livestock quarters. When used as directed, **Oxonia Active** is specifically designed to disinfect, deodorize and clean inanimate, hard, surfaces such as walls, floors, sink tops, furniture, operating tables, kennel runs, cages and feeding and watering equipment. In addition **Oxonia Active** will deodorize those areas which are generally hard to keep fresh smelling such as garbage storage areas, empty garbage bins and cans, and any other areas which are prone to odors caused by microorganisms.

All treated equipment that will contact feed or drinking water must be rinsed with potable water before reuse.

For heavily soiled areas, a pre-cleaning step is required. Prepare a fresh solution for each use.

DISINFECTION OF POULTRY PREMISES, TRUCKS, COOPS AND CRATES

1. Remove all poultry and feeds from premises, trucks, coops and crates.
2. Remove all litter and droppings from floors, walls and surfaces of facilities occupied or traversed by poultry.
3. Empty all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with a detergent and rinse with water.
5. Saturate surfaces with a 0.3% solution of **Oxonia Active** for a period of 10 minutes.
6. Ventilate buildings, coops and other closed spaces. Do not house poultry or employ equipment until treatment has been absorbed, set or dried.
7. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with a detergent and rinse with potable water before reuse.

See your Klenzade or Airkem Representative for specific recommendations for all cleaning and rinsing requirements.

POULTRY HATCHERY DISINFECTION

Clean out any remaining eggs and chicks. Remove gross soils, such as litter, down, shell fragments or other hatching related debris. Empty all racks and other equipment. Thoroughly wash all surfaces, including floors, walls, conveyors, trays and water systems with a recommended detergent. Rinse thoroughly with water. Apply a 0.30% solution of **Oxonia Active** with a mop, cloth, brush or coarse spray. Wet all surfaces and allow to remain wet for 10 minutes. Ventilate buildings and other closed spaces. Allow to dry before reintroducing eggs.

DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARNS, KENNELS, HUTCHES, ETC.)

Remove animals and feed from facilities. Remove litter, waste matter and gross soils. Empty all troughs, rack and other feeding and watering equipment. Wash surfaces with a recommended alkaline detergent, by manual, foam, or spray application. Rinse with water. Apply a 0.30% solution of **Oxonia Active** with a mop, cloth, brush or coarse spray. Wet all surfaces and allow to remain wet for 10 minutes. Ventilate buildings and other closed spaces. Allow to air dry before reintroducing animals.

VIRUCIDAL ACTIVITY - Poultry and Livestock Pathogens

Oxonia Active is useful as a disinfectant against viruses pathogenic to poultry, such as Influenza A (H10N7), Newcastle Disease virus, Infectious bronchitis virus, and Reovirus (C08), as well as bovine pathogens such as Infectious bovine rhinotracheitis (IBR) and Parainfluenza 3 Virus.

FOR SANITIZING OF HATCHING EGGS

Prepare a solution of **Oxonia Active** by diluting 2 oz product with 5 gallons of water. As eggs are gathered or prior to setting, apply solution as a coarse spray so as to lightly wet all shell surfaces.

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 sterilizing solution by diluting 6.4 ounces **Oxonia Active** concentrate per each gallon of water (50 mL/liter) (5.0% v/v). Circulate, coarse spray, or flood the sterilizing solution through the system. All surfaces should be exposed to the sterilizing solution for a minimum exposure time based on the product solution temperature. The following time and temperature relationships are required:

Oxonia Active Concentration	Temperature	Time
5%	68°F (20°C)	6 hours
5%	122°F (50°C)	20 minutes
5%	176°F (80°C)	5 minutes

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

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 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 gl) Do not reuse empty containers. Wrap container and put in trash.
(4, 15, 30, 50 gl 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 gl 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.

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