

1677-129

5-11-2001

1/9

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 11 2001

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

Attention: John G. Wood, Director
Product Registration and Compliance

Subject: Oxonia Active
EPA Registration Number 1677-129
Amendment Dated April 6, 2001

The Agency is conditionally approving your amendment to the registration of the product referenced above under authority of FIFRA Section 3(c)(7)(B). This amendment allows use of the subject product as a virucide against the animal pathogen "Foot and Mouth Disease (FMD)Virus."

This amendment will expire automatically on June 1, 2002. In addition, during the 1 year period that this amendment is effective, it will be subject to the conditions listed below

The following information must be submitted, and found acceptable by December 31, 2001 and the Agency must determine that the data is acceptable by June 1, 2002.

Failure to satisfy the data requirements listed below may result in EPA issuing a notice to cancel this amendment under FIFRA section 6(e). This conditional registration will expire automatically on June 1, 2002. Sale or distribution of the subject product bearing labeling claims for the Foot and Mouth Disease Virucidal use will be illegal if the requirements of this acceptance letter are not satisfied..

A. The product must be tested, and found to be effective, against the FMD virus in an approved facility (Institute for Animal Health).

B. Testing must be conducted on two batches of the product.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Page 2

C. The performance standard is total inactivation of the virus or a 3-log reduction if Cytotoxicity is present.

A stamped accepted copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7510C)

Enclosure

3/9

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

DISINFECTANT FOR THE PHARMACEUTICAL AND COSMETIC INDUSTRY

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 11 2001

Active Ingredients:

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

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

1677-129

KEEP OUT OF REACH OF CHILDREN DANGER

PRECAUTIONARY STATEMENTS - HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: 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 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. 1677-129

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

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)

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

4/9

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 1.3 to 2.0 ounces **Oxonia Active** concentrate per 4 gallons of water (0.25 - 0.4% v/v concentration). At this dilution **Oxonia Active** is effective against *Staphylococcus aureus*, *Escherichia coli*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, *Salmonella typhimurium*, *Pseudomonas aeruginosa* and *Vibrio cholerae*. Also effective against organisms found in the brewing industry, *Saccharomyces cerevisiae*, *Pediococcus damnosus* and *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 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 1.3 to 2.0 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 0.25% dilution (1.3 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.

ACCEPTED
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in EPA Letter Dated:
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5/9

SANITIZING NON-FOOD CONTACT SURFACES

Preclean surfaces as directed above. Sanitize non-food contact surfaces such as floors, walls, tables, chairs, benches, drains, troughs, and drip pans with 1 oz Oxonia Active per 8 gal 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, *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

Oxonia Active is an effective foam sanitizer of precleaned non-food contact surfaces, such as boots, floors, walls, drains, and associated equipment. For this application, prepare a solution of 0.2% v/v (1 oz per 4 gallons water) Oxonia Active and 0.13% v/v (0.8 oz per 4 gallons water) Liquid K. For example, in four gallons of water, add 1 ounce of Oxonia Active and 0.8 ounces of Liquid K. Liquid K is the only approved foam generator. Apply solution as a foam using recommended equipment such as a Super Foamer. 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 0.3% to 3.0% (3 oz. to 30 oz. per 8 gallons of water) Oxonia Active 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 beverage spoilage organisms that include *Pediococcus damnosus*, *Lactobacillus malefermentans*, and *Saccharomyces cerevisiae* apply 0.5 - 4.0% (5 oz. to 40 oz. per 8 gallons of water) of Oxonia Active 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 CONTAINERS

To sanitize precleaned or new returnable or non-returnable containers, apply Oxonia Active at a concentration of 1.0% to 4.0% (10 oz. to 40 oz. per 8 gallons of water) at a temperature of 40 to 60 deg. C for at least 7 seconds. At these conditions, Oxonia Active is effective against *Staphylococcus aureus*, *Escherichia coli*, *Salmonella typhi*, *Pediococcus damnosus*, *Lactobacillus malefermentans*, and *Saccharomyces cerevisiae*. 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 that include *Pediococcus damnosus*, *Lactobacillus malefermentans*, and *Saccharomyces cerevisiae* apply Oxonia Active as a 0.5 to 2.0% (5 oz. to 20 oz. per 8 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 A SURFACTANT

To reduce the number of beverage spoilage organisms that include *Pediococcus damnosus*, *Lactobacillus malefermentans*, and *Saccharomyces cerevisiae*, add a 1.0 to 4.0% (10 oz. to 40 oz. per 8 gallons of water) solution of Oxonia Active to a 0.05 - 0.5% concentration (1 oz per 16 gallons to 2 oz per 3 gallons) of [insert name of surfactant blend] 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. Contact Ecolab for a list of acceptable surfactants.

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6/9

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, 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. Not for use on food preparation surfaces, medical devices or medical equipment surfaces.

COMBINATION DISINFECTION AND CLEANING

Oxonia Active is effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Salmonella enteritidis*, *Salmonella typhimurium*, *Proteus vulgaris*, *Streptococcus pyogenes* and *Histoplasma capsulatum** at 0.4% (4 oz per 8 gallons of water) 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. Prepare a disinfecting and cleaning solution by diluting 4 ounces **Oxonia Active** in 8 gallons of water (0.4% v/v). 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 0.4% (4 oz. per 8 gallons of water) in the presence of 5% blood serum, 500 ppm hard water and residual soap scum on 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 0.4% (4 oz. per 8 gallons of water) **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.

DISINFECTING PHARMACEUTICAL AND COSMETIC SURFACES

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

This product is effective against *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa* at 0.4% (4 oz in 8 gallons water) 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.

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7/9

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.

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

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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 0.4% (4 oz. per 8 gallons of water) 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 Ecolab or Airkem Representative for specific recommendations for all cleaning and rinsing requirements.

1677-129

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 0.4% (4 oz. per 8 gallons of water) 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 (BARN, KENNELS, HUTCHES)

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 0.4% (4 oz. per 8 gallons of water) 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. Effective against *Aspergillus fumigatus*.

VIRUCIDAL ACTIVITY - Poultry and Livestock Pathogens

Oxonia Active is useful as a disinfectant against viruses pathogenic to poultry that include Influenza A (H10N7), Newcastle Disease virus, Infectious bronchitis virus, Reovirus (C0₈), as well as bovine and other livestock pathogens, that include Infectious bovine rhinotracheitis (IBR), Parainfluenza 3 Virus, and the foot & mouth disease virus (Aphthovirus).

BACTERIOSTATIC

At 0.04% (1 oz. per 20 gallons of water) **Oxonia Active** is effective at inhibiting the growth of bacteria when used in the presence of 500 ppm hard water and organic soil.

8/9

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.

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9/9

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 a sterile 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.

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

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