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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Ms. Ann M. Oxford Klenzade, Division of Ecolab, Inc. **Ecolab Center** St. Paul, MN 55102

MAY 15 1992

/n/n

Dear Ms. Oxford:

Subject: Oxonia Active

EPA Registration No. 1677-129

Your Resubmission Dated January 30, 1992

Your submission of corrections to previously submitted studies and revised labeling for the subject product has completed review. The following comments apply.

The corrections and labeling, referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, are acceptable on an interim basis with the following comments.

- 1. Enclosed you will find a copy of the review by the Efficacy Evaluation and Technical Management Section of the Antimicrobial Program Branch (OPPTS/OPP/RD). The deficiencies of this resubmission are outlined in this review. All deficiencies must be corrected and submitted to complete the registration record.
- 2. As outlined in the labeling section of the efficacy review, some food contact surface claims are not acceptable under our current requirements. You do not have to remove the claims at this time, but you must provide a letter of authorization from the Food and Drug Administration clearing your formulation for use on these surfaces. For further information contact:

Mitchell Cheeseman, Ph.D. Indirect Additives Branch, HFF-335 Division of Food and Color Additives Food and Drug Administration 200 C Street, S.W. Washington, DC 20204 Telephone: (202) 254-9511

CONCURRENCES YMBOL OFFICIAL FILE COPY EFA Form 1320-1A (1/90)

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The change in the subject product's basic name from "Oxysan" to "Oxonia Active" has been noted and placed in the registration file.

Enclosed is a copy of the accepted stamped labeling for your records.

If you have any questions about these comments, please call Bill Wooge at (703) 305-5295.

Sincerely yours,

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Ruth G. Douglas Product Manager (32) Antimicrobial Program Branch Registration Division (H7504C)

OXONIA ACTIVE

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

Active Ingredients:

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.

EPA Reg. No. 1677-129

EPA Est.

1677-MN-1 (P), 1677-IA-1 (H), 60156-IL-1 (SI) Superscript refers to first letter of date code

Net Contents:

50 U.S. Gals. (189 l) 30 U.S. Gals. (113.5 l) 15 U.S. Gals. (56.8 l) 4 U.S. Gals. (15.1 l) 1 U.S. Gal. (3.78 l)

ACCEPTED with COMMERTIA in EPA Letter Codes.

Klenzade, Division of Ecolab Inc. Ecolab Center

St. Paul, MN 55102

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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

Oxonia Active acid sanitizer is recommended for use on hard, non-porous, inanimate 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 CaCo₃.

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 1.8 ounces **Cxonia** Active per 4 gallons of water (0.20 - 0.35% v/v concentration). At this dilution **Oxonia** Active is effective against Staphylococcus aureus, 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. Use immersion, 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 equipment thoroughly. Do not rinse.

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 hard, non-porous, inanimate, 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 damncsus* and *Lactobacillus buchneri*. All surfaces should be exposed to the sanitizing solution for a period of not less than 5 minutes. No rinse necessary.

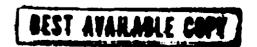
DISINFECTION

Oxonia Active disinfects as it cleans in one operation. Oxonia Active can be used to disinfect floors, walls and other hard, non-porous, inanimate, environmental surfaces such as tables, chairs, countertops, bathroom fixtures, sinks, bed frames, shelves, : racks, carts, refrigerators, coolers, glazed tile, linoleum, vinyl, asphalt, glazed pórcéiain, plastic (such as polypropylene and polyethylene), stainless steel, or glass.

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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, agriculture and livestock farms, food and beverage manufacturing and processing plants, dietary areas, office buildings, recreational facilities, retail and wholesale establishments.

COMBINATION DISINFECTION AND CLEANING

Oxonia Active is effective against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa at 0.3% (1.6 oz/4 gl) in hard water (500 ppm & CaCO3), 5% blood serum and dried soap film residue on hard, non-porous, inanimate, environmental surfaces at 21 deg C. For heavily soiled areas a precleaning step is required. Apply solution with mop, cloth, sponge, brush, scrubber, powered or mechanical 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 more often when the solution becomes diluted or sciled.

TUBERCULOCIDAL

Oxonia Active passes the requirements as a tuberculocide at 0.3% (1.6 oz/4 gl) in the presence of 5% blood serum, 500 ppm hard water and residual soap scum on hard porous and non-porous, inanimate, environmental surfaces at 21 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.

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 such as Klenzade's High Foaming Liquid Cleaner II or Airkem's High Foaming Degreaser and rinse with water.

5. Saturate surfaces with a 0.3% solution (1.6 oz/4 gl) 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 such as Klenzade's High Foaming Liquid Cleaner II or Airkem's High Foaming Degreaser, and rinse with potable water before reuse.

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

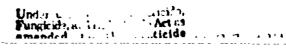
NOTE: This product in its use solutions is compatible with stainless stad! and aluminum surfaces. If product is intended to be used on any other surface, it is recommended that you apply product to a smaller test area to determine compatibility before proceeding with its use.

For other specialized cleaning and sanitizing operations, consult your Klenzade representative.

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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) Trip's 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.

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