

PM 33

1677-159

7/7/99

Page 185

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 07 1999

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

RE: TX-8848
EPA Reg. No. 1677-159
Your Amendment Dated 5/17/99

The Amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add the sites and use directions for sanitizing pre-cleaned, hard, non-porous surfaces in the pharmaceutical and cosmetic industry, modifying the "Precautionary Statements" and "Statement of Practical Treatment", and adding the 4 gallon and 300 gallon tote sizes, is acceptable with the following comments.

REQUIRED LABEL CHANGES

You must submit five copies of a revised label which address the following changes.

1. According to the EPA Product Reregistration letter and acute inhalation review for this product, dated 9/23/98 and 9/10/98, respectively, an adequate inhalation study needs to be submitted, found acceptable, and a toxicity category needs to be assigned. We understand that the required inhalation study has been submitted in June 1999, and that the EPA review is not completed. Without this EPA review, we can not assign a proper toxicity category for the acute inhalation test. The following acute toxicity categories were assigned in the memo dated 9/10/98.

- Oral - III
- Dermal - I
- Inhalation- pending study currently under review
- Eye- I
- Skin- I
- Sensitization- Waived

Your revised "Precautionary Statements" and "Statement of Practical Treatment" labeling accurately reflect the assigned categories. The labeling involving inhalation also reflects toxicity category II (same as for TGAI). This inhalation toxicity category and associated label language is acceptable, subject to the results of the inhalation study which is in review. At that time you may need to provide additional label changes to prevent over labeling or under labeling

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2. In the "Sanitizing Food Contact Surfaces" and "Sanitizing Pharmaceutical and Cosmetic Surfaces" use directions, you must correct the lower ppm concentration numbers shown for each active ingredient. You must change the 100 ppm number for peroxyacetic acid to **130 ppm**, and change the 640 ppm number for hydrogen peroxide to **800 ppm**.

3. In the "Sanitizing Food Contact Surfaces" section, change the last sentence to read as follows,

"No potable water rinse is required if product is used at a 0.4% v/v concentration of TX-8848, or less."

A copy of the submitted label stamped "Accepted With Comments" is 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.

Sincerely,



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

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TX-8848

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

LIQUID SANITIZER FOR PHARMACEUTICAL AND COSMETIC INDUSTRIES

ACTIVE INGREDIENTS:

Hydrogen Peroxide 27.00%
Peroxyacetic Acid 4.50%

INERT INGREDIENTS 68.50%

**FOR COMMERCIAL USE ONLY
STRONG OXIDIZING AGENT**

**KEEP OUT OF REACH OF CHILDREN
DANGER**

PRECAUTIONARY STATEMENTS - HAZARDS TO HUMAN 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.

EPA Reg. No. 1677-159
EPA Est. 60156-IL-1 (SI)

**ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUL 07 1999**

Ecolab Inc.
Ecolab Center
St. Paul, MN 55102

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

1677-159

Net Contents:	50 U.S. Gals. (189 l)
	4 U.S. Gals. (15.1 l)
	1 U.S. Gal.
	300 U.S. Gals. tote

PULP & PAPER MILLS

To control bacteria, fungi, and fresh water organisms (such as protozoa and filamentous bacteria) in paper, paperboard, or nonwoven process water and influent water systems. TX-8848 should be dosed at a convenient point in the process or influent systems. Suitable dosing points include but are not limited to; stock chests, pulpers, and white water loop and white water storage systems and influent water streams. Not for use in the manufacture of pulp and paper board intended for food contact.

Severely fouled systems should be cleaned before adding TX-8848.

FREQUENCY & DOSE

A. INFLUENT WATER SYSTEMS

TX-8848 should be fed continuously to incoming fresh water streams (nonpotable use only) at dosages ranging from 5 - 500 ppm.

B. MILL PROCESS WATERS

1. Continuous Feed - TX-8848 should be fed continuously at dosages ranging from 5 - 500 ppm. This range may be equivalent to 0.4 - 40 lbs (5.5 - 553 ounces) TX-8848 per ton (dry basis) of pulp or paper produced.
2. Intermittent Feed - TX-8848 should be fed intermittently at dosages ranging from 5 - 500 ppm. This dosage may be equivalent to 0.4 - 40 lbs (5.5 - 553 ounces) TX-8848 per ton (dry basis) of pulp or paper produced during the feed period.
3. Shock Dose - TX-8848 should be shock dosed at dosages ranging from 50 - 1000 ppm. This dosage may be equivalent to 4 - 82 lbs (55 - 1140 ounces) TX-8848 per ton (dry basis) of pulp or paper produced during the feed period.

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 the 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 gal) Do not reuse empty containers. Wrap container and put in trash. (4 gallon, 50 gallon) 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 tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

**ACCEPTED
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