

1677-159

7/15/2003

Page 185

JUL 15 2003

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

**Subject: TX-8848  
EPA Reg. No. 1677-159  
Your Amendment Dated 4/7/03**

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to provide a revised label which updates the "First Aid" statements as required by PR Notice 2001-1, and changes other "Precautionary Statements" in response to the EPA product re-registration letter dated 3/27/02, and makes other label changes, is acceptable providing you make the following corrections/clarification, and submit 3 copies of a final printed label reflecting only these changes within 90 days from the date of this letter.

**Label Page 1/3**

Change the word "make" to "made" in "...make out of any waterproof material".

**Label Page 2/3**

1. In the use directions for "Sanitizing Food Contact Surfaces", immediately after the sentence beginning with, "This will provide 130...", add the following missing sentence, "Rinse all surfaces thoroughly with the sanitizing solution and maintain a contact time of at least 1 minute". This identical sentence is also in the subsequent pharmaceutical section

2. In the "Note for mechanical operations", add "additional" to "...reused for additional sanitizing...".

**Label Page 3/3**

1. In steps #1 and #2 of the section for "Mill process waters", correct "5-500 ppm" to "10-1000 ppm as peroxyacetic acid".

2. In step #3 of the section for "Mill process waters", correct "50-100 ppm" to "100-2000 ppm as peroxyacetic acid".

3. Change "may be equivalent" in all three steps to "is equivalent"

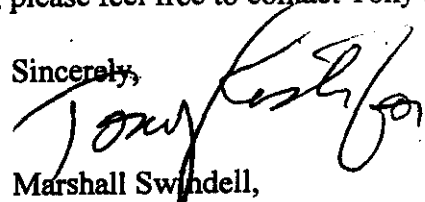
**CONCURRENCES**

<b>SYMBOL</b>							
<b>SURNAME</b>							
<b>DATE</b>							

Please include a copy of this letter with any response. A copy of the accepted label stamped "Accepted With Comments" is attached.

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

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

# TX-8848

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

LIQUID SANITIZER FOR THE PHARMACEUTICAL AND COSMETIC INDUSTRY

**Active Ingredients:**

Hydrogen Peroxide.....27.0%  
Peroxyacetic Acid.....4.5%

**Inert Ingredients:**.....68.5%  
**Total:** .....100.0%

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:  
JUL 15 2003

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.  
1677-159

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**  
**PELIGRO**

**PRECAUTIONARY STATEMENTS - HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER: CORROSIVE:** Causes irreversible eye damage and skin burns. Fatal if absorbed through the skin or inhaled. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Prolonged or frequently repeated skin contact may cause an allergic reaction in some individuals. Do not breathe vapor or spray mist. Wash thoroughly after handling with soap and water and before eating, drinking or using tobacco. Remove contaminated clothing and wash clothing before reuse. The following Personal Protective Equipment (PPE) should be used when handling the product: coveralls over long-sleeved shirt and long pants, socks and chemical-resistant footwear, goggles or face shield, chemical-resistant gloves (such as rubber or make out of any waterproof material), chemical-resistant apron. Wear a mask or pesticide respirator jointly approved by Mine Safety and Health Administration and the National Institute for Occupational Safety and Health.

**FIRST AID**

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 -20 minutes. Call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or going for treatment.

**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:** This pesticide is toxic to birds, fish, and aquatic invertebrates. 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.

Dispense directly from original container. Use only clean synthetic hoses made of materials such as Teflon, polyethylene, or polystyrene. Do not use rubber hoses. If concentrate must be transferred to another container, use only clean, vented containers made of synthetic materials such as Teflon, polyethylene or polystyrene.

#### **DIRECTIONS FOR USE**

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

#### **SANITIZATION**

**TX-8848** acid sanitizer is recommended for use on pre-cleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in dairies, dairy farms, 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  $\text{CaCO}_3$ .

#### **SANITIZING FOOD CONTACT SURFACES**

Prior to sanitizing, remove gross food particles, and then wash with a detergent solution, followed by a potable water rinse. Prepare sanitizing solution by diluting 1 2/3 – 2 1/2 fluid ounces **TX-8848** concentrate per 5 gallons of water (0.25 – 0.40% v/v concentration). This will provide 130 – 200 ppm peroxyacetic acid and 800 – 1200 ppm of hydrogen peroxide. Fill closed systems such as piping, tanks, fillers, evaporators, and pasteurizers with the sanitizing solution at a temperature range of 5°C (45°F) to 40°C (104°F) for a contact time of at least 1 minute. Allow surfaces to drain thoroughly before resuming food processing operations. No potable water rinse is required if product is used at a 0.4% v/v concentration of **TX-8848** or less.

#### **SANITIZING PHARMACEUTICAL AND COSMETIC SURFACES**

**TX-8848** acid sanitizer is recommended for use on pre-cleaned, hard, non-porous, environmental surfaces such as floors, walls and processing equipment in pharmaceutical and cosmetic processing facilities.

This product is effective as a sanitizer when solution is prepared in water of up to 500 ppm hardness as  $\text{CaCO}_3$ . Prior to sanitizing, remove gross soil, wash with a detergent solution, and follow with a clean water rinse. Prepare sanitizing solution by diluting 1 2/3 – 2 1/2 fluid ounces **TX-8848** concentrate per 5 gallons of water (0.25 – 0.40% v/v concentration). This will provide 130 – 200 ppm peroxyacetic acid and 800 – 1200 ppm of hydrogen peroxide. Rinse all surfaces thoroughly with the sanitizing solution and maintain a contact time of at least 1 minute. Product contact surfaces must be rinsed with sterile water.

**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.

**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.

#### **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 water 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**.

ACCEPTED  
with COMMENTS  
in EPA Letter Dated:

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575

**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 50-100 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**

**PESTICIDE 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.

**FOR COMMERCIAL USE ONLY  
STRONG OXIDIZING AGENT**

EPA Reg. No. 1677-159

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

<b>Net Contents:</b>	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 Inc.  
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St. Paul, MN 55102

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