

1677-185

10/25/2006

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

**102506**

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Mr. Brian C. Brosdahl  
Director of International Product Registration & Compliance for,  
Ecolab, Inc.  
370 N. Wasbasha Street  
Saint Paul, MN 55102

Subject: Enviro San  
EPA Registration Number 1677-185  
Your Amendment Dated October 21<sup>st</sup>, 2005  
EPA Received Date October 24<sup>th</sup>, 2005

The following amendment(s), submitted in connection with registration under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to include directions for commercial sterilization of food packaging materials and equipment, is acceptable provided you make the labeling revisions:

Under the "Commercial Sterilization of Food Packaging Materials" section, revise the statement, "This product can be used to sterilize.....Low Acid Dairy Foods" to read "This product may be used to sterilize polyethylene terephthalate (PET) packaging for aseptic packaging of low acid dairy food that has a scheduled process accepted by FDA. The aseptic food processing operation must comply with all applicable FDA regulations, including but not limited to 21 CFR parts 108, 110, 113, and/or 114. Use in an aseptic food processing operation includes testing required for the process validation".

Under the "Commercial Sterilization of Manufacturing, Filling, and Packaging Equipment for Food Processing" section, revise the statement, "This product can be used in FDA approved processes for Aseptic Packaging of Low Acids" to read "This product may be used for Aseptic Packaging of Low Acid Foods that has a scheduled process by FDA. The aseptic food processing operation must comply with all applicable FDA regulations, including but not limited to 21 CFR parts 108, 110, 113, and/or 114. Use in an aseptic food processing operation includes testing required for the process validation.

The submitted efficacy data support the use of the product, Enviro San with ES-1000, as a sanitizer, as a commercial sterilant for food packaging materials against the following microorganisms on hard, non-porous surfaces for a contact time of 19 seconds.

Clostridium sporogenes (ATCC 3584)  
Bacillus cereus (ATCC 14579)  
Bacillus subtilis (ATCC 19659)

The Agency's review of these data is enclosed.

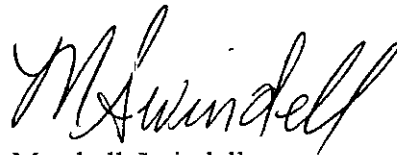
A stamped copy of the labeling accepted with conditions is enclosed. Submit three (3) copies of your final printed labeling before distributing, or selling the product bearing the revised labeling.

Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

If the above conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

Should you have any questions or comments concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6273.

Sincerely



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

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# ENVIRO SAN

COMMERCIAL STERILANT FOR ASEPTIC PACKAGING OF FOODS

COMMERCIAL STERILANT FOR ASEPTIC MANUFACTURING AND PACKAGING  
EQUIPMENT FOR FOOD PROCESSING

## Active Ingredients:

Hydrogen Peroxide ..... 11.2%  
Peroxyacetic Acid..... 15.2%

Inert Ingredients ..... 73.6%

Total ..... 100.0%

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**with COMMENTS**  
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**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**

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

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## 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.

### 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 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 SWALLOWED:** Call a poison control center or doctor 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 a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026**

**OUTSIDE NORTH AMERICA, CALL 1-651-222-5352**

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

**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.

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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.

**COMMERCIAL STERILIZATION**

**ENVIRO SAN** can be used in food processing aseptic packaging systems as a commercial sterilant to treat clean, non-porous food packaging materials and equipment. This product is effective as a commercial sterilant in conjunction with **ES-1000** when the solution is prepared in water of up to 500 ppm hardness.

**COMMERCIAL STERILIZATION OF FOOD PACKAGING MATERIALS**

Commercially sterilize clean, non-porous food packaging materials with a concentration of 5.0 ounces of **ENVIRO SAN** concentrate per 1.0 gallon of water (6597 ppm peroxyacetic acid by weight) and 0.2 ounces of **ES-1000** concentrate per 1.0 gallon of water (1500 ppm by weight) at a temperature of 60 - 65°C. Sterilization solution must be maintained at a minimum of 4100 ppm peroxyacetic acid and 1000 ppm ES-1000. For example, in one gallon of water add 5.0 ounces of **Enviro San** and 0.2 ounces of **ES-1000**. Use immersion, coarse spray or circulation techniques as appropriate to sterilize the food packaging material. Surfaces should be exposed to the solution for a period of not less than 19 seconds unless a longer time is specified by the governing food processing authority. After thorough draining, rinse surfaces with a disinfected water rinse free of pathogenic bacteria or sterile water. This product when used per label directions is effective against *Bacillus cereus*, *Bacillus subtilis*, and *Clostridium sporogenes* in water up to 500 ppm hardness.

This product may be used to sterilize polyethylene terephthalate (PET) packaging for aseptic packaging of low acid dairy foods that has a schedule process accepted by FDA. The aseptic food processing operation must comply with all applicable FDA regulations, including, but not limited to, 21 CFR parts 108, 110, 113, and/or 114. Use in an aseptic food processing operation includes testing required for the process validation.

**COMMERCIAL STERILIZATION OF MANUFACTURING, FILLING, AND PACKAGING EQUIPMENT FOR FOOD PROCESSING**

Prior to use of this product, remove gross soil particles from equipment surfaces, thoroughly clean surfaces, and follow with a potable water rinse. Commercially sterilize clean manufacturing, filling, and packaging equipment with a concentration of 5.0 ounces of **ENVIRO SAN** concentrate per 1.0 gallon of water (6597 ppm peroxyacetic acid by weight) and 0.2 ounces of **ES-1000** concentrate per 1.0 gallon of water (1500 ppm by weight) at a temperature of 60 - 65°C. Sterilization solution must be maintained at a minimum of 4100 ppm peroxyacetic acid and 1000 ppm ES-1000. For example, in one gallon of water add 3.4 ounces of **Enviro San** and 0.2 ounces of **ES-1000**. Use immersion, coarse spray or circulation techniques as appropriate to sterilize the equipment. Surfaces should be exposed to the solution for a period of not less than 19 seconds unless a longer time is specified by the governing food processing authority. After thorough draining, rinse surfaces with a disinfected water rinse free of pathogenic bacteria or sterile water. This product when used per label directions is effective against *Bacillus cereus*, *Bacillus subtilis*, and *Clostridium sporogenes* in water up to 500 ppm hardness.

This product may be used for Aseptic Packaging of Low Acid Foods that has a scheduled process accepted by FDA. The aseptic food processing operation must comply with all applicable FDA regulations, including, but not limited to, 21 CFR parts 108, 110, 113, and/or 114. Use in an aseptic food processing operation includes testing required for the process validation.

**This product is not for use as a sterilant on medical devices.**

**SANITIZATION**

**ENVIRO SAN** acid sanitizer is recommended for use on pre-cleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment 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.

**SANITIZING FOOD CONTACT SURFACES**

Prior to use of this product, remove gross soil particles from surfaces, thoroughly clean surfaces, and follow with a potable water rinse. Sanitize clean surfaces with a concentration of 0.10 - 0.18% v/v (1000

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to 1800 ppm v/v or 1 to 1.8 ounces per 8 gallons of water) at room temperature. Use immersion, coarse spray or circulation techniques as appropriate to sanitize the surfaces. All surfaces should be exposed to the sanitizing solution for a period of not less than one minute unless otherwise specified by governing sanitary code. Allow surfaces to drain thoroughly and air dry. Do not rinse. This product when used per label directions is effective against *Staphylococcus aureus* and *Escherichia coli*.

#### SANITIZING NON-FOOD CONTACT SURFACES

Prior to use of this product, remove gross soil particles from surfaces, thoroughly clean surfaces, and follow with a potable water rinse. Sanitize clean surfaces with a concentration of 0.2 - 1.5% v/v (2000 to 15,000 ppm v/v or 2 oz. to 15 oz. per 8 gallons of water) at a temperature of 25 to 45 °C. Use immersion, coarse spray or circulation techniques as appropriate to sanitize the surfaces. All surfaces should be exposed to the sanitizing solution for a period of not less than five minutes unless otherwise specified by governing sanitary code. Allow surfaces to drain thoroughly before resuming operations. Drainage may be followed by a potable or sterile water rinse. This product when used per label directions is effective against *Enterobacter aerogenes*, *Escherichia coli*, *Listeria monocytogenes*, *Pseudomonas aeruginosa*, *Salmonella typhimurium*, *Staphylococcus aureus*, *Pediococcus damnosus*, and *Lactobacillus malefermentans*.

#### ANTIMICROBIAL RINSE OF PRECLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS

To reduce the number of beverage spoilage organisms, *Lactobacillus malefermentans*, *Saccharomyces cerevisiae* and *Alicyclobacillus acidoterrestris*, apply Enviro San at a concentration of 2 to 8 ounces concentrate per 3 gallons of water (0.58% to 2.3% weight percent) at a temperature of 40 to 65 °C for at least 7 seconds. After thorough draining, rinse surfaces with a disinfected water rinse free of pathogenic bacteria or sterile water.

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

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 gal and less) Do not reuse empty containers. Wrap container and put in trash.

(4, 30, 50 gal 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.

(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

#### Net Contents:

96 ounces  
1 U.S. Gal. (3.78 L)  
4 U.S. Gals. (15.1 L)  
50 U.S. Gals. (189 L)  
30 U.S. Gals. (113.5 L)

Manufactured by:  
Ecolab Inc.  
370 N. Wabasha Street  
St. Paul, MN 55102

EPA Reg. No. 1677-185  
EPA Est.: 1677-MN-1 (P), 30156-IL-1 (SI), 1677-CA-2 (R),  
1677-TX-1 (D), 1677-OH-1 (H), 1677-IL-2 (J), 1677-PR-1 (B),  
1677-CA-1 (S), 1677-NJ-1 (W), 1677-GA-1 (M), 1677-WV-1 (V)  
Superscript refers to first letter of date code

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