

1677-185

7/2/2009

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

JUL 02 2009

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Ms. Rhonda Schulz  
Associate Director of Product Registration & Compliance for,  
Ecolab, Inc.  
370 North Wabasha Street  
Saint Paul, MN 55102

Subject: Enviro San  
EPA Registration Number 1677-185  
Your Amendment Dated March 6<sup>th</sup>, 2009  
EPA Received Date March 6<sup>th</sup>, 2009

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, to revise the product labeling to revise the product labeling to clarify the "Directions for Use", is acceptable.

A stamped copy of the labeling is enclosed for your records.

A copy of the efficacy review is enclosed with this letter.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell".

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

SANITIZER FOR PRECLEANED SURFACES

## Active Ingredients:

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

Inert Ingredients ..... 73.6%

Total ..... 100.0%

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

JUL - 2 2009

KEEP OUT OF REACH OF CHILDREN

**DANGER**

Under the Federal Insecticide,  
Fungicide and Rodenticide Act as  
amended for " " "  
registered under EPA REG. NO 1677185

## 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 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.

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8**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 alone or in conjunction with **ES-1000** when the solution is prepared in water of up to 500 ppm hardness. Refer to Directions for Use to determine the suitable application with alternative concentrations and contact times. Where a minimum concentration is specified in the use instructions a test kit or titration method is recommended for verifying that the appropriate concentration is maintained.

**COMMERCIAL STERILIZATION OF FOOD PACKAGING MATERIALS****ENVIRO SAN with ES-1000 at 60°C**

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 - 70°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.

**ENVIRO SAN with ES-1000 at 50°C**

Commercially sterilize clean, non-porous food packaging materials with a concentration of 3.7 ounces of **ENVIRO SAN** concentrate per 1.0 gallon of water (4838 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 50 - 60°C. Sterilization solution must be maintained at a minimum of 3000 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 40 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.

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

JUL - 2 2009

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 1677-185

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**ENVIRO SAN alone at 60°C**

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) at a temperature of 60°C - 70°C. Sterilization solution must be maintained at a minimum of 4100 ppm peroxyacetic acid. 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 subtilis*, and *Clostridium sporogenes* in water up to 500 ppm hardness.

**ENVIRO SAN alone at 50°C**

Commercially sterile clean, non-porous food packaging materials with a concentration of 3.7 ounces of **ENVIRO SAN** concentrate per 1.0 gallon of water (4838 ppm peroxyacetic acid by weight) at a temperature of 50 - 60°C. Sterilization solution must be maintained at a minimum of 3000 ppm peroxyacetic acid. 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 40 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 subtilis* and *Clostridium sporogenes*.

The alternative concentrations and conditions for commercial sterilization of food packaging materials described above are summarized in the following table:

	(ENVIRO SAN + ES-1000 at 60°C)	ENVIRO SAN + ES-1000 at 50°C	ENVIRO SAN alone at 60°C	ENVIRO SAN alone at 50°C
<b>Prepare solution:</b>				
ENVIRO SAN (oz/gallon)	5.0	3.7	5.0	3.7
ENVIRO SAN (POAA by weight)	6597	4838	6597	4838
ES-1000 (oz/gallon)	0.2	0.2	N/A (zero)	N/A (zero)
ES-1000 (ppm by weight)	1500	1500	N/A (zero)	N/A (zero)
Temperature (°C)	60-70	50-60	60-70	50-60
<b>Sterilizing solution must be maintained at:</b>				
POAA concentration (ppm)	4100	3000	4100	3000
ES-1000 concentration (ppm)	1000	1000	N/A (zero)	N/A (zero)
Contact time (seconds)	19	40	19	40
Effective against the following organisms	<i>Bacillus cereus</i> <i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>	<i>Bacillus cereus</i> <i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>	<i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>	<i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>

JUL - 2 2009

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1677-85

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This product may be used to sterilize polyethylene terephthalate (PET) and high density polyethylene (HDPE) packaging for aseptic packaging of low acid 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**

ENVIRO SAN can be used to sterilize manufacturing equipment such as pipelines, pumps, tanks, vats, fillers, evaporators, and pasteurizers. Refer to the equipment manufacturer's instructions to determine how to sterilize the equipment in place or to disassemble the equipment for sterilization by immersion. It is suitable for use on equipment or surfaces composed of glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel, or glass.

#### **ENVIRO SAN with ES-1000 at 60°C**

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 - 70°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 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.

#### **ENVIRO SAN with ES-1000 at 50°C**

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 3.7 ounces of **ENVIRO SAN** concentrate per 1.0 gallon of water (4838 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 50 - 60°C. Sterilization solution must be maintained at a minimum of 3000 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 equipment. Surfaces should be exposed to the solution for a period of not less than 40 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.

ACCEPTED  
BY THE GOVERNMENT  
EPA UNDER REG. NO. 1677-185  
JUL - 2 2009  
Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 1677-185

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**ENVIRO SAN alone at 60°C**

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) at a temperature of 60 - 70°C. Sterilization solution must be maintained at a minimum of 4100 ppm peroxyacetic acid. 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 subtilis*, and *Clostridium sporogenes* in water up to 500 ppm hardness

**ENVIRO SAN alone at 50°C**

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 3.7 ounces of **ENVIRO SAN** concentrate per 1.0 gallon of water (4838 ppm peroxyacetic acid by weight) at a temperature of 50 - 60°C. Sterilization solution must be maintained at a minimum of 3000 ppm. 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 40 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 subtilis*, and *Clostridium sporogenes* in water up to 500 ppm hardness

ACCEPTED  
with COMMENTS

EPA Letter Dated:

JUL - 27-2009

The alternative concentrations and conditions for commercial sterilization of manufacturing, filling and packaging equipment for food processing described above are summarized in the following table:

	ENVIRO SAN + ES-1000 at 60°C	ENVIRO SAN + ES-1000 at 50°C	ENVIRO SAN alone at 60°C	ENVIRO SAN alone at 50°C
<b>Prepare solution:</b>				
ENVIRO SAN (oz/gallon)	5.0	3.7	5.0	3.7
ENVIRO SAN (POAA by weight)	6597	4838	6597	4838
ES-1000 (oz/gallon)	0.2	0.2	N/A (zero)	N/A (zero)
ES-1000 (ppm by weight)	1500	1500	N/A (zero)	N/A (zero)
Temperature (°C)	60-70	50-60	60-70	50-60
<b>Sterilizing solution must be maintained at:</b>				
POAA concentration (ppm)	4100	3000	4100	3000
ES-1000 concentration (ppm)	1000	1000	N/A (zero)	N/A (zero)
Contact time (seconds)	19	40	19	40
Effective against the following organisms	<i>Bacillus cereus</i> <i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>	<i>Bacillus cereus</i> <i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>	<i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>	<i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 1677-185

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.

**This product is not for use as a sterilant or high level disinfectant 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 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.

### **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 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*, *Alicyclobacillus acidoterrestris* and *Penicillium digitatum*, apply ENVIRO SAN at a concentration of 2 to 8 ounces concentrate per 3 gallons of water (0.58% to 2.3% by weight) 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.

To reduce the number of beverage spoilage organisms, *Lactobacillus malefermentans*, *Pediococcus damnosus*, *Saccharomyces cerevisiae* and *Penicillium digitatum*, apply ENVIRO SAN at a concentration of 6 to 15 ounces concentrate per 5 gallons of water (1.0% to 2.6% by

weight) at ambient temperature for at least 10 seconds. After thorough draining, rinse surfaces with a disinfected water rinse free of pathogenic bacteria or sterile water.

**BOOSTER FOR ALKALINE AND ACIDIC DETERGENTS TO CLEAN FOOD PROCESSING EQUIPMENT:**

ENVIRO SAN is an effective oxygen bleach cleaning booster for use with alkaline and acidic detergents. For cleaning applications as a detergent booster, use 2 to 8 ounces concentrate per 3 gallons of water (0.58% to 2.3% by weight) to aid in the removal of organic soils. All hard non-porous food contact surfaces treated with this boosted detergent must be rinsed thoroughly with a potable water rinse followed by sanitizing with an approved food contact surface sanitizer.

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

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:**

(≤ 55-gallons rigid) Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying.

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

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

JUL - 2 2009

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
FOR COMMERCIAL USE ONLY pesticide,  
STRONG OXIDIZING AGENT Under EPA Reg. No. 1677-185

**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. No.: 1677-MN-1 (P), 60156-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-GA-1 (M), 1677-WV-1 (V)  
Superscript refers to first letter of date code