

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

March 16, 2015

Ms. Tamera McKeehan Sr. Regulatory Specialist for, Ecolab Inc. 370 N. Wabasha Street St. Paul, MN 55102

Subject: Label Amendment – to add sulfur reducing non-public health claims, storage

disposal language, make minor clarification changes as per CDPR's request

Product Name: Enviro San

EPA Registration Number: 1677-185 Application Date: December 14, 2014

Decision Number: 499068

Dear Ms. McKeehan:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Karen M. Leavy by phone at (703)-308-6237, or via email at Leavy.Karen@epa.gov.

Sincerely,

Elizabeth K Wathins

Elizabeth Watkins Acting Product Manager 33 Regulatory Management Branch I Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure

ENVIRO SAN

COMMERCIAL STERILANT FOR ASEPTIC PACKAGING OF FOODS

COMMERCIAL STERILANT FOR ASEPTIC MANUFACTURING AND PACKAGING EQUIPMENT FOR FOOD PROCESSING

SANITIZER FOR PRE-CLEANED SURFACES

Active Ingredients:

Hydrogen Peroxide	11.2%
Peroxyacetic Acid	
Inert (Other) Ingredients	
Total	

KEEP OUT OF REACH OF CHILDREN DANGER

ACCEPTED

03/16/2015

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 1677-185

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 with soap and water after handling and before eating, drinking, chewing gum, er using tobacco or using the toilet. 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.

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** or **ES-2000** 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 must 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 3.7 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 must 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.

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 must 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 must 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*.

Enviro San with ES-2000 at 50°C (4000 ppm POAA)

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 0.01 ounces of *ES-2000* concentrate per 1.0 gallon of water (100 ppm by weight) at a minimum temperature of 50°C. Sterilization solution must be maintained at a minimum of 4000 ppm peroxyacetic acid and a maximum of 500 ppm H₂O₂. *ES-2000* must be added to the recirculating system to achieve 500 ppm H₂O₂ or less and not to exceed 650 ppm *ES-2000*. For example, in one gallon of water add 5.0 ounces of *ENVIRO SAN* and 0.01 ounces of *ES-2000*. Use immersion, coarse spray or circulation techniques as appropriate to sterilize the food packaging material. Surfaces must be exposed to the solution for a period of not less than 15 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-2000 at 50°C (3000 ppm POAA)

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 0.01 ounces of *ES-2000* concentrate per 1.0 gallon of water (100 ppm by weight) at a minimum temperature of 50°C. Sterilization solution must be maintained at a minimum of 3000 ppm peroxyacetic acid and a maximum of 500 ppm H₂O₂. *ES-2000* must be added to the recirculating system to achieve 500 ppm H₂O₂ or less and not to exceed 650 ppm *ES-2000*. For example, in one gallon of water add 3.7 ounces of *ENVIRO SAN* and 0.01 ounces of *ES-2000*. Use immersion, coarse spray or circulation techniques as appropriate to sterilize the food packaging material. Surfaces must be exposed to the solution for a period of not less than 35 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.

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	Enviro San + ES-2000 at 50°C	Enviro San + ES-2000 at 50°C
Prepare solution:						
Enviro San (oz/gallon)	5.0	3.7	5.0	3.7	5.0	3.7
Enviro San (POAA by weight)	6597	4838	6597	4838	6597	4838
ES-1000 (oz/gallon)	0.2	0.2	N/A (zero)	N/A (zero)	N/A (zero)	N/A (zero)
ES-1000 (ppm by weight)	1500	1500	N/A (zero)	N/A (zero)	N/A (zero)	N/A (zero)
ES-2000 (oz/gallon)	N/A (zero)	N/A (zero)	N/A (zero)	N/A (zero)	0.01	0.01
ES-2000 (ppm by weight)	N/A (zero)	N/A (zero)	N/A (zero)	N/A (zero)	100	100
Temperature (°C)	02-09	20-60	02-09	20-60	>50	>50
Sterilizing solution must be maintained at:						
POAA concentration (ppm)	4100	3000	4100	3000	4000	3000
ES-1000 concentration (ppm)	1000	1000	N/A (zero)	N/A (zero)	N/A (zero)	N/A (zero)
H ₂ O ₂ concentration (ppm)	>3000	>2200	>3000	>2200	<500	<200
ES-2000 concentration (ppm)	N/A (zero)	N/A (zero)	N/A (zero)	N/A (zero)	As needed to	As needed to
					achieve <500	achieve <500
					ppm H ₂ O ₂ , not	ppm H ₂ O ₂ , not
					to exceed 650	to exceed 650
					ppm ES-2000	ppm ES-2000
Contact time (seconds)	19	40	19	40	15	35
Effective against the	Bacillus cereus	Bacillus cereus	Bacillus subtilis	Bacillus	Bacillus	Bacillus
following organisms	Bacillus subtilis	Bacillus subtilis	Clostridium sporogenes	snptilis	cereus	cereus
	Clostridium	Clostridium		Clostridium	Bacillus	Bacillus
	sporogenes	sporogenes		sporogenes	subtilis	subtilis
					Clostridium	Clostridium
					sporogenes	sporogenes

This product may be used to sterilize food packaging materials 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 must 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 3.7ounces 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 3.7 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 must 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.

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 must 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 must 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

Enviro San with ES-2000 at 50°C (4000 ppm POAA)

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 exposed to the s 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 0.01 ounces of *ES-2000* concentrate per 1.0 gallon of water (100 ppm by weight) at a minimum temperature of 50°C. Sterilization solution must be maintained at a minimum of 4000 ppm peroxyacetic acid and a maximum of 500 ppm H₂O₂. *ES-2000* must be added to the recirculating system to achieve 500 ppm H₂O₂ or less and not to exceed 650 ppm *ES-2000*. For example, in one gallon of water add 5.0 ounces of *ENVIRO SAN* and 0.01 ounces of *ES-2000*. Use immersion, coarse spray or circulation techniques as appropriate to sterilize the equipment. Surfaces must be olution for a period of not less than 15 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-2000 at 50°C (3000 ppm POAA)

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 0.01 ounces of *ES-2000* concentrate per 1.0 gallon of water (100 ppm by weight) at a temperature of 50°C. Sterilization solution must be maintained at a minimum of 3000 ppm peroxyacetic acid and a maximum of 500 ppm H₂O₂. *ES-2000* must be added to the recirculating system to achieve 500 ppm H₂O₂ or less and not to exceed 650 ppm *ES-2000*. For example, in one gallon of water add 3.7 ounces of *ENVIRO SAN* and 0.01 ounces of *ES-2000*. Use immersion, coarse spray or circulation techniques as appropriate to sterilize the equipment. Surfaces must be exposed to the solution for a period of not less than 35 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.

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	Enviro San + ES-2000 at 50°C	Enviro San + ES-2000 at 50°C
Prepare solution:						
Enviro San (oz/gallon)	5.0	3.7	5.0	3.7	2.0	3.7
Enviro San (POAA by weight)	6597	4838	6597	4838	6597	4838
ES-1000 (oz/gallon)	0.2	0.2	N/A (zero)	N/A (zero)	N/A (zero)	N/A (zero)
ES-1000 (ppm by weight)	1500	1500	N/A (zero)	N/A (zero)	N/A (zero)	N/A (zero)
ES-2000 (oz/gallon)	N/A (zero)	N/A (zero)	N/A (zero)	N/A (zero)	0.01	0.01
ES-2000 (ppm by weight)	N/A (zero)	N/A (zero)	N/A (zero)	N/A (zero)	100	100
Temperature (°C)	02-09	20-60	02-09	20-60	>20	>50
Sterilizing solution must be maintained at:						
POAA concentration (ppm)	4100	3000	4100	3000	4000	3000
ES-1000 concentration (ppm)	1000	1000	N/A (zero)	N/A (zero)	N/A (zero)	N/A (zero)
H ₂ O ₂ concentration (ppm)	>3000	>2200	>3000	>2200	<200	<500
ES-2000 concentration (ppm)	N/A (zero)	N/A (zero)	N/A (zero)	N/A (zero)	As needed to	As needed to
					achieve <500	achieve <500
					ppm H ₂ O ₂ , not	ppm H_2O_2 , not
					to exceed 650	to exceed 650
					ppm ES-2000	ppm ES-2000
Contact time (seconds)	19	40	19	40	15	35
Effective against the	Bacillus cereus	Bacillus cereus	Bacillus subtilis	Bacillus	Bacillus	Bacillus
following organisms	Bacillus subtilis	Bacillus subtilis	Clostridium sporogenes	subtilis	cereus	cereus
	Clostridium	Clostridium		Clostridium	Bacillus	Bacillus
	sporogenes	sporogenes		sporogenes	subtilis	subtilis
					Clostridium	Clostridium
					sporogenes	sporogenes

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 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 must 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 sanitizer the surfaces. All surfaces must 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 PRE-CLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS

To reduce the numbers of beverage spoilage organisms apply Enviro San at a concentration of 2 to 15 ounces concentrate per 3 gallons of water (0.58% to 4.4% 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 apply Enviro San at a concentration of 6 to 25 ounces concentrate per 5 gallons of water (1.0% to 4.4% 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.

To reduce the number of beverage spoilage organisms apply **ENVIRO SAN** at a concentration of 0.8 ounces of concentrate per 1.0 gallon of water (1000 ppm peroxyacetic acid by weight) and ES-2000 at a concentration of 0.01 ounces of concentrate per 1.0 gallon of water (100 ppm by weight) at a minimum temperature of 30°C for at least 3 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.

FOR ANTIMICROBIAL, H₂S AND FES MANAGEMENT USES WITH AQUEOUS TREATMENT FLUIDS IN SUBTERRANEAN OILFIELD AND GAS-FIELD WELL OPERATIONS SUCH AS WELL DRILLING, FORMATION FRACTURING, PRODUCTIVITY ENHANCEMENT AND SECONDARY RECOVERY

ENVIRO SAN can be used for control of microorganisms commonly found in oilfiled systems which can lead to reservoir souring, localized corrosion of metals, and/or biofouling. **ENVIRO SAN** can also be used to control H₂S and FeS. **ENVIRO SAN** must be introduced through a closed mixed/loading and delivery transfer system equipped with a metering device that is appropriate for its intended uses.

<u>DRILLING MUDS, FRACTURING FLUIDS, WELL SQUEEZED FLUIDS. (Not for use in California.)</u>

Enviro San Alone:

For the preservation of drilling muds, workover and completion fluids and other product susceptible to contamination, pre-mix *ENVIRO SAN* with the fluid or add directly at the point of use at 3.75 fluid ounces per 1000 gallons of water (5 ppm peroxyacetic acid by weight) to 75.5 fluid ounces per 1000 gallons of water (100 ppm peroxyacetic acid by weight) as required. Depending on the severity of the contamination, initial application may be added up to 755 fluid ounces per 1000 gallons of water (1000 ppm peroxyacetic acid by weight). In H₂S and FeS

applications, use concentrations of up to 1510 fluid ounces per 1000 gallons of water (2000 ppm peroxyacetic acid by weight) may be required.

Enviro San with ES-2000 adjuvant:

For the preservation of drilling muds, workover, completion fluids and other products susceptible to contamination, pre-mix EnviroSan with the fluid or add directly at the point of use 3.75 to 755 fluid ounces of *ENVIRO SAN* per 1000 gallons of water (5 - 1000 ppm peroxyacetic acid by weight) and 0.036 to 110 ounces of *ES-2000* concentrate per 1000 gallons of water (0.34 – 1005 ppm by weight). In H_2S and FeS applications, use concentrations of up to 1510 fluid ounces per 1000 gallons of water (2000 ppm peroxyacetic acid by weight) may be required.

FLOODING, INJECTION AND PRODUCED WATER (Not for use in California.)

Enviro San Alone

For Water Flooding operations, add *ENVIRO SAN* initially at 3.75 fluid ounces per 1000 gallons of water (5ppm peroxyacetic acid by weight) to 75.5 fluid ounces per 1000 gallons of water (100 ppm peroxyacetic acid by weight) and repeat until control is achieved. Subsequent treatment may be continued on a weekly basis or as required. Injection wells associated with gas storage systems may be treated up to 100 ppm (peroxyacetic acid by weight) when diluted in the formation water. Any additional top-up water must be treated as required. For hydrostatic systems, apply 3.75 fluid ounces per 1000 gallons of water (5 ppm peroxyacetic acid by weight) to 75.5 fluid ounces per 1000 gallons of water (100 ppm peroxyacetic acid by weight) depending on the water quality and the duration of the shut-in. Depending on the severity of the contamination, initial application may be added up to 755 fluid ounces per 1000 gallons of water (1000 ppm peroxyacetic acid by weight). In H₂S and FeS applications, use concentrations of up to 1510 fluid ounces per 1000 gallons of water (2000 ppm peroxyacetic acid by weight) may be required.

Enviro San with ES-2000 adjuvant:

For water flooding operations pre-mix *ENVIRO SAN* with the fluid or add directly at the point of use 3.75 to 755 fluid ounces per 1000 gallons of water (5 - 1000 ppm peroxyacetic acid by weight) and 0.036 to 110 ounces of *ES-2000* concentrate per 1000 gallons of water (0.34 – 1005 ppm by weight). In H_2S and FeS applications, use concentrations of up to 1510 fluid ounces per 1000 gallons of water (2000 ppm peroxyacetic acid by weight) may be required.

PIPELINE AND TANK MAINTENACE (Not for use in California.)

Enviro San Alone

For microbial control in water-bottoms in crude and refined hydrocarbon storage tanks, piping and transportation systems. Apply 3.75 fluid ounces of *ENVIRO SAN* per 1000 gallons of water (5 ppm peroxyacetic acid by weight) to 75.5 fluid ounces per 1000 gallons of water (100 ppm peroxyacetic acid by weight) in the aqueous phase, directly injected into the water-bottom, pipeline or may be added to the hydrocarbon phase. Treatment may be applied daily or monthly for both storage and transportation systems as needed. Depending on the severity of the contamination, initial application may be added up to 755 fluid ounces per 1000 gallons of water (1000 ppm peroxyacetic acid by weight). In H₂S and FeS applications, use concentrations of up to 1510 fluid ounces per 1000 gallons of water (2000 ppm peroxyacetic acid by weight) may be required.

Enviro San with ES-2000 adjuvant:

For microbial control in water-bottoms in crude and refined hydrocarbon storage tanks, piping and transportation systems pre-mix *ENVIRO SAN* with the fluid or add directly at the point of Page 11 of 14

use 3.75 to 755 fluid ounces per 1000 gallons of water (5 - 1000 ppm peroxyacetic acid by weight) and 0.036 to 110 ounces of **ES-2000** concentrate per 1000 gallons of water (0.34 – 1005 ppm by weight). In H_2S and FeS applications, use concentrations of up to 1510 fluid ounces per 1000 gallons of water (2000 ppm peroxyacetic acid by weight) may be required.

In all oilfield and gas-field well operation applications always prepare a new solution daily to ensure effectiveness. Do not re-use solutions. Dispose of unused solution.

STORAGE & DISPOSAL:

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

PESTICIDE STORAGE: Product must be kept cool and in a vented container to avoid any explosion hazard.

NEVER RETURN PRODUCT TO THE ORIGINAL CONTAINER AFTER IT HAS BEEN REMOVED. Avoid all contaminants, especially dirt, caustic, reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of decomposition, isolate container, douse container with cool water and dilute with large volumes of water.

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 HANDLING AND DISPOSAL:

FOR USE ON REFILLABLE CONTAINERS WITH INDUSTRIAL/COMMERCIAL/INSTITUIONAL PUBLIC HEALTH USES:

Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller.

RESIDUE REMOVAL INSTRUCTIONS: For refillable containers. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

(2.5 gal bladder in box) Non-refillable container. Do not reuse or refill this container. Remove empty bladder from outer corrugated box. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer box and bladder for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(For containers 5 gallons or less.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(For containers >5-55 gallons.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

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

FOR COMMERCIAL USE STRONG OXIDIZING AGENT

Made in USA

EPA Reg. No. 1677-185 EPA Est. No.: 1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2 (R),

Net Contents:

96 ounces

1 U.S. Gal. (3.78 L)

4 U.S. Gals. (15.1 L)

30 U.S. Gals. (189 L) 50 U.S. Gals. (113.5 L) 265 U.S. Gals (1003.1 L)

1677-TX-1 (D), 1677-IL-2 (J), 1677-GA-1 (M), 1677-WV-1 (V)

Superscript refers to first letter of date code

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

SECONDARY CONTAINER LABEL

(Note to reviewer: This secondary/use dilution container label will be used only when the product is diluted according to label directions at 5 oz. or less per gallon of water. Other

dilutions must use concentrate signal word and precautionary statements from page 1. The use dilution is to be prepared and used by end user and will not be sold or distributed.)

ENVIRO SAN

Concentrate Ingredient Statement

Active Ingredients:

Hydrogen Peroxide	11.2%
Peroxyacetic Acid	
Inert Ingredients:	<u>73.6%</u>
Total:	100.0%

Diluted product in this container is _____ oz. per gallon water.

KEEP OUT OF REACH OF CHILDREN

DANGER

After product is diluted in accordance with the directions for use, protective gloves, mask and respirator are not required. Use of protective eyewear is still required after the product is diluted in accordance with the directions for use. Harmful if swallowed. Wash thoroughly after handling with soap and water before eating, drinking or using tobacco.

Refer to the product label for complete First Aid instructions.

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 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.

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

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

The product in this container must be diluted at the use rate of 5 oz. or less per gallon of water as directed on the concentrate product label. Refer to concentrate label for use directions.

Use solution prepared by end user. **NOT TO BE SOLD OR DISTRIBUTED.**

EPA Reg. No. 1677-185