

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

OCT 3 0 2008

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 June 21st, 2008 EPA Received Date July 3rd, 2008

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 include three additional sterilant uses, is acceptable.

The efficacy data provided for three additional sterilant uses of the product support the use of the product, Enviro San, as a sterilant against the following microorganisms on hard, non-porous surfaces in the presence of 500 ppm hard water for the listed conditions:

Bacillus cereus	40 seconds; 50degrees Celsius; product plus adjuvant
Bacillus subtilis	40 seconds; 50 degrees Celsius; product plus adjuvant
Clostridium sporogenes	40 seconds;50 degrees Celsius; product plus adjuvant
Bacillus subtilis	40 seconds; 50 degrees Celsius; product only
Clostridium sporogenes	40 seconds; 50 degrees Celsius; product only
Bacillus subtilis	40 seconds; 50 degrees Celsius; product only
Clostridium sporogenes	40 seconds; 50 degrees Celsius; product only
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Efficacy data provided for the three additional sterilant uses of the product demonstrated complete killing in the subcultures of the required number of carriers (i.e, 360 hard, non-porous carriers) tested against the requirednumber of product lots (i.e., 3). Neutralization confirmation testing showed positive growth of the microorganisms. The viability controls were positive for growth. Purity controls were reported as pure. The sterility controls did not show growth. Test spores showed resistance to acid for at least 2 minutes.

Make the following labeling revisions to read as follows:

- 1. The proposed label does not include directions or claims of effectiveness for the additional sterilant uses:
 - a. 40 seconds contact time for use of the product, Enviro San, with an adjuvant, ES-1000, at 50 degrees Celsius.
 - b. 40 seconds contact time for use of the product, Enviro San, alone at 50 degrees Celsius.
 - c. 19 seconds contact time for use of the product use of the product, Enviro San, alone at 60 degrees Celsius.

The efficacy data provided support the three additional sterilant uses of the product.

- 2. Under the Environmental Hazards section of the proposed label, revise "permitting authority" to read "the permitting authority".
- 3. In the first paragraph on page 3 of the proposed label, change "equipment dairies" to read "equipment in dairies".
- 4. Under the "Commercial Sterilization" section of the proposed label, as appropriate, include a statement similar to the following: "When sterilizing complex equipment such as [identify the type of equipment intended for treatment, in addition to any description of surface composition]: Fully dis-Assemble the equipment according to the manufacturer's instructions; clean and Rinse all hollow areas making sure that the sterilize the equipment according to product label directions making sure that all hollow areas are filled with the use Solution; avoid entrapment of air bubbles); and completely reassemble under aseptic conditions.
- 5. Under the "Sanitizing Food Contact Surfaces" section and the "Sanitizing Non-Food Contact Surfaces" section of the proposed label, revise "to sanitize the surfaces" to read "to sanitize the surfaces".
- 6. Under the "Sanitizing Non-Food Contact Surfaces" section of the proposed label, revise "to sanitize the surfaces" to read "sanitize the surfaces".
- 7. Under the "Pesticide Storage" section of the proposed label, add instructions that specify what to do if the product or use solution leaks or spills from its container.
- 8. Under the "Container Disposal" section of the proposed label, revise "or incineration" to read "or by incineration".

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,

Marshall Swindell

Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7510P)

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:	•	with COMMENTS
Hydrogen Peroxide	11.2%	EPA Letter Dated:
Peroxyacetic Acid		007 9 0 2000
Inert Ingredients	73.6%	OCT 3 0 2008
Total	100.0%	Under the Foderal Insecticide,

KEEP OUT OF REACH OF CHILDRENamended, for the perticule, registered under EPA Reg. N

Fungicide, and Rodenticide Act as amended, for the perticide, registered under EPA Reg. No. 1677-185

ACCEPTED

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 MÉDICAL 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.

ACCEP6/21/08 with COMMENTS EPA Letter Dated:

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling -ingicide, and Rodenborde Act as

COMMERCIAL STERILIZATION

amended, for the perfords, ENVIRO SAN can be used in food processing aseptic packaging systems as a commercials. 1607180 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.

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.

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
Prepare solution:				
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
Sterilizing solution must				
be maintained at:				
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	Bacillus cereus	Bacillus cereus	Bacillus subtilis	Bacillus subtilis
following organisms	Bacillus subtilis	Bacillus subtilis	Clostridium	Clostridium
	Clostridium sporogenes	Clostridium sporogenes	sporogenes	sporogenes

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 FEFA Letter Dated: Validation.

OCT 3 0 2008

Under the Federal Inscribitle, Fungicide, and Robentiside Act as amended, for the periode, registered under Fifth Reg. 1908–1601-1885

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

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 3.7ounces 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 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

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 appointed sterilize the equipment. Surfaces should be exposed to the solution for a period condition of the solution for a period condition for a period condition for a period condition for a pe

Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 1671-185

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

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
Prepare solution:				
Enviro San (oz/gallon)	5.0	3.7	5.0	3.7
Enviro San (POAA by weight)	6597	4838	6597	4838
ES-1000 (oz/gailon)	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
Sterilizing solution must				
be maintained at:			,	
POAA concentration (ppm)	4100	3000	4100	3000
ES-1000 concentration	1000	1000	N/A (zero)	N/A (zero)
(ppm)				
Contact time (seconds)	19	40	19	40
Effective against the following organisms	Bacillus cereus Bacillus subtilis	Bacillus cereus Bacillus subtilis	Bacillus subtilis Clostridium	Bacillus subtilis Clostridium
	Clostridium sporogenes	Clostridium sporogenes	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 validatiac CEPTED with COMMENTS

This product is not for use as a sterilant or high level disinfectant on medical devices Dated:

OCT 3 0 2008

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

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 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 sanitizer 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 *Pencillium 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 damnosis*, *Saccharomyces cerevisiae* and *Pencillium 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 companies of the person detergents. For cleaning applications as a detergent booster, use 2 to 8 ouncasion control of organics of the person of water (0.58% to 2.3% by weight) to aid in the removal of organics of the part porporous 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 satisfaces to the property of the person of th

Under the Federal Insecticida Fungicide, and Rodents or sot as amended, for the perticipations registered under EPA Reg. No. 1677-185

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.

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. 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

ACCEPTED
with COMMENTS
EPA Letter Dated:
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Under the Federal Insecticide, Fungicide, and kodenticide, with amended, for the pesticide, registered under EPA Reg. No. 1671-185