

65402-3

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

NOV 13 2010

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Ms. LuAnn Maloney  
Regulatory Manager for,  
FMC Corporation  
1735 Market Street  
Philadelphia, PA 19103

Subject: VigorOx<sup>®</sup> SP-15 Antimicrobial Agent  
EPA Registration Number 65402-3  
Your Amendment dated June 16<sup>th</sup>, 2010  
EPA Received Date June 17<sup>th</sup>, 2010

The amendment referred to above, submitted in connection with under section 3(c)(7)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to expand the claim to reduce 99.9% of pathogenic foodborne bacteria in processing water for fruits and vegetables, is acceptable.

The proposed label claim is acceptable regarding the use of the product as an antimicrobial agent to reduce foodborne pathogenic bacteria in processing waters of fruits and vegetables at a contact time of 90 seconds. The provided efficacy data supports this claim.

The contact time of 90 seconds appears as optional language. Please note that the contact time is required language for proper use of the product.

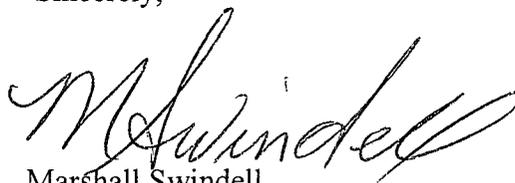
A stamped copy of the labeling is enclosed. Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling.

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.

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

Sincerely,

A handwritten signature in black ink, appearing to read "M. Swindell". The signature is fluid and cursive, with the first letter "M" being particularly large and stylized.

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

# VigorOx<sup>®</sup> SP-15 Antimicrobial Agent

EPA Registration No. 65402-3  
EPA Est. No. 00279-NY-003

## For Industrial Use Only

Active Ingredients:	Peroxyacetic Acid .....	15%
	Hydrogen Peroxide .....	10%
Inert Ingredients:	.....	75%
Total:	.....	100%

## KEEP OUT OF REACH OF CHILDREN DANGER

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for biofouling and slime control in:

- Pulp and paper mill systems
- Recirculating process and cooling water systems
- Coating preservation
- Dispersed pigment preservation

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for institutional/industrial sanitizing of previously cleaned non-porous food contact surfaces in:

- Dairies, Wineries, Breweries and Beverage Plants
- Meat and Poultry Processing/Packaging Plants
- Milk and Dairy Products Processing/Packing Plants
- Seafood and Produce Processing/Packing Plants
- Food Processing/Packing Plants
- Egg Processing/Packing Equipment Surfaces
- Eating Establishments

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for Institutional/ industrial sanitizing of previously cleaned non-porous food contact surfaces such as:

- Eating, Drinking, and Food Preparation Utensils
- Tableware
- Plastic, Glass and Metal Bottles (rinse)

For Organic Production. VigorOx<sup>®</sup> SP-15 Antimicrobial Agent may be used in rinse or wash water on products labeled as organic in food processing facilities on commodities that will be further processed. For use as a sanitizer on food contact surfaces in contact with products labeled as organic.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for use as a coarse spray for surfaces to be sanitized.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent can be used with the HRS<sup>™</sup> and HRS<sup>™</sup> II foaming agents. For food-contact applications, the foaming agent must be used in compliance with applicable regulations under the Federal Food, Drug and Cosmetic Act.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent can be used with the non-foaming agent, Paradigm<sup>™</sup>, as an antimicrobial container rinse and for hard, non-porous surface sanitization and disinfection.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for sanitizing surfaces such as packinghouse conveyers and harvesting equipment and containers. It is effective against plant pathogens such as *Xanthomonas campestris* (*axonopodis*) pathovars citrumelo (citrus canker surrogate).

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for sanitization of hatching eggs.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for use in fogging applications as an adjunct to acceptable manual cleaning and sanitizing room surfaces.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for porous and non-porous hard surface sterilization except aseptic packaging which is limited to hard surfaces only.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for use in the disinfection of hard surfaces in general commercial and medical environments and as an antimicrobial rinse of Pre-cleaned or New Returnable or Non-Returnable Containers.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent can be used for reducing pathogenic foodborne bacteria in processing waters for fruits and vegetables.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for use as a dip or spray wash to control the growth of non-public health microorganisms that may cause decay and/or spoilage on raw, post-harvest and fresh cut, fruits and vegetables.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for use in process water that contacts raw, post-harvest, fresh-cut and processed fruits and vegetables.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for use in aseptic food processing on food packaging materials to achieve commercial sterility.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for use in wastewater and sewage effluent disinfectant in public and private treatment facilities.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for use in agricultural water and irrigation systems

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is for use in commercial and Institutional /Industrial laundry operations for disinfection and sanitization.

ACCEPTED  
with COMMENTS  
in EPA Reg. No. 65402-3

NOV 13 2010

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended by Act No. 101-645,  
registered under EPA Reg. No.

65402-3

Net Contents: Gallons                      Pounds

**Precautionary Statements**  
**Hazards to Humans and Domestic Animals**

**DANGER**

Corrosive, causes eye and skin damage. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Wash thoroughly with soap and water after handling. Do not breathe vapor or spray mist. Do not enter an enclosed area without proper respiratory protection.

**Physical or Chemical Hazards**

Strong oxidizing agent. Mix only with water. VigorOx® SP-15 Antimicrobial Agent is not combustible; however, at temperatures exceeding 156°F, decomposition occurs, releasing oxygen. The oxygen released could initiate or promote combustion of other materials.

**Environmental Hazards**

This pesticide is toxic to birds, mammals, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with 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.

Any solution released from the system should be diluted with water and tested for residuals to ensure that there is less than 3 ppm peroxygen remaining.

**First Aid**

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

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

**Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

ACCEPTED  
 with COMMENTS  
 in ERM 12/10/10  
 NOV 13 2010  
 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the product registered under EPA Reg. No. 65402-3

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**FMC Corporation**  
**Peroxygens Division**  
**1735 Market Street**  
**Philadelphia Pennsylvania 19103**

**Storage and Disposal**

**Storage**

**NEVER RETURN VigorOx® SP-15 Antimicrobial Agent 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.

Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden pallets.

**Procedure for Leak or Spill**

Stop leak if this can be done without risk. Shut off ignition sources; no flames, smoking, flares, or spark producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

**Disposal**

**Pesticide Disposal**

If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal.

VigorOx® SP-15 Antimicrobial Agent which is to be discarded should be disposed of as hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

**Container Disposal**

**Nonrefillable containers less than 5 gallons.** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times.

**Nonrefillable containers greater than or equal to 5 gallons.** Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the 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 into 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 for disposal. Repeat this procedure two more times. Empty drums are not returnable to FMC unless special arrangements have been made. Dispose of drums in accordance with local, state, and Federal regulations.

**All Refillable containers.** 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 refill is the responsibility of the refiller. 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. Return to FMC for reuse.

**Directions for Use**

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

**Biofouling Control in Pulp and Paper Mill Systems**

For use in the manufacture of paper and paperboard intended for food and non-food contact.

VigorOx® SP-15 Antimicrobial Agent can be used to control bacterial, fungal and yeast growth in pulp, paper and paperboard mills.

1. Severely fouled systems should be cleaned before initial treatment with VigorOx® SP-15 Antimicrobial Agent. Refer to the plant operations manual for directions for cleaning severely fouled systems. The product should be added directly to the system and not mixed with any other chemicals or additives. Other chemicals can be added separately. Contamination with other chemicals could result in product decomposition.
2. Add the VigorOx® SP-15 Antimicrobial Agent at a point in the system where it can be mixed uniformly with the pulp, e.g., the beater, hydropulper, fan pump, broke pump etc.
3. Intermittent feed method: Apply 0.5 lb to 1.2 lb (7 to 16 fluid ounces) of VigorOx® SP-15 Antimicrobial Agent per ton (dry basis) of pulp or paper produced for two to three hours every eight-hour shift. Maintain a concentration that provides adequate control. Daily rate could change depending on the severity of the biofouling.
4. Continuous feed method: Initially, use the intermittent feed method to achieve control. When control is accomplished, apply VigorOx® SP-15 Antimicrobial Agent continuously at the rate determined adequate for intermittent control. Then reduce the rate of addition to the lowest level sufficient to maintain control. Depending on the severity of the biofouling, control usually can be maintained using a continuous rate of 0.2 to 1.2 lb (2.6 to 16 fluid ounces) of VigorOx® SP-15 Antimicrobial Agent solution per ton (dry basis) of pulp or paper produced on a continuous basis. This will provide 15 to 90 ppm of peroxyacetic acid and 10 to 60 ppm of hydrogen peroxide.

**Control of Bacteria and Fungi in Dispersed Pigments**

VigorOx® SP-15 Antimicrobial Agent can be used to control bacteria and fungi in the manufacture and storage of dispersed pigments used in paint and paper production such as kaolin clay, titanium dioxide, calcium carbonate, calcium sulfate, barium sulfate, magnesium silicate and kieselguhr.

Apply 0.2 to 1.2 lb (2.6 to 16 fluid ounces) (90 to 545 grams) of VigorOx® SP-15 Antimicrobial Agent solution to each 1,000 lb (454 Kg) of fluid. This will provide 200 to 1200 ppm of product (30 to 180 ppm of peroxyacetic acid and 20 to 120 ppm of hydrogen peroxide).

**Control of Slime Forming Bacteria in Recirculating Cooling Water Systems (Cooling Towers, Evaporative Condensers) and Non-Food Contact Water Systems (Pulp and Paper Mill Water Systems).**

VigorOx® SP-15 Antimicrobial Agent is for use in treating raw (make-up) and process waters, closed and opened loop systems such as heat exchangers, wet scrubbers, cooling towers, evaporative condensers and recirculating industrial process waters, such as pulp and paper mill water systems.

ACCEPTED  
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 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, this pesticide is registered under EPL Reg. No. 65402-3

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1. Severely fouled systems should be cleaned before adding the VigorOx<sup>®</sup> SP-15 Antimicrobial Agent solution. Refer to the system operation manual for directions to clean severely fouled systems. The product should be added directly to the system and not mixed with any other chemicals or additives. Other chemicals should be added separately. Contamination with other chemicals could result in product decomposition.
2. Add the VigorOx<sup>®</sup> SP-15 Antimicrobial Agent solution at a point in the system where uniform mixing and even distribution will occur.
3. Intermittent feed method: When the system is noticeably fouled, apply 0.8 to 1.2 lb (10 to 16 fluid ounces) of VigorOx<sup>®</sup> SP-15 Antimicrobial Agent solution per 1000 gallons of water in the system. Repeat until control is achieved. When microbial control is evident, add 1.0 lb (14 fluid ounces) of the solution per 1000 gallons of water in the system every day, or as needed, to maintain control. The daily dose rate could vary depending upon the severity of the biofouling.
4. Continuous feed method: Initial dose – When the system is just noticeably fouled, apply 0.8 to 1.2 lb (10 to 16 fluid ounces) of VigorOx<sup>®</sup> SP-15 Antimicrobial Agent solution per 1000 gallons of water in the system. When microbial control is achieved, start adding VigorOx<sup>™</sup> SP-15 Antimicrobial Agent solution continuously at a rate of 1.0 lb (14 fluid ounces) per 1000 gallons of water (provides 17 ppm peroxyacetic acid and 12 ppm of hydrogen peroxide). Then reduce the rate of addition to a level sufficient to maintain control. The dose rate may have to be adjusted to account for losses due to blowdown and evaporation. Add 1.4 fluid ounces of VigorOx<sup>™</sup> SP-15 Antimicrobial Agent for every 100 gals of make-up water.

**Control of Bacteria and Fungi in Coating Preservation**

Do not use for coatings preservation applications involving direct or indirect food contact.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent can be used as an in-container preservative for the control of bacteria and fungi in water-based coatings such as paper coatings.

- Add 0.2 to 1.2 lb (2.6 to 16 fluid ounces) (90 to 545 grams) of VigorOx<sup>®</sup> SP-15 Antimicrobial Agent solution to each 1,000 lbs (454 Kg) of water (provides 200 to 1200 ppm of product or 30 to 180 ppm peroxyacetic acid and 20 to 120 ppm of hydrogen peroxide).

**Aseptic Food Processing Operations**

This product may be used to achieve commercial sterility of food packaging prior to fill and of equipment used in aseptic food processing applications.

**Food Packaging Materials**

Apply VigorOx<sup>®</sup> SP-15 Antimicrobial Agent on the exterior and interior of food containers and closure systems (caps, seals, etc.). Apply 4000 ppm peroxyacetic acid at a minimum temperature of 65°C. The solution must remain in contact with the packaging surface for a minimum of 20 seconds. Rinse containers with sterile water prior to filling with processed food; in lieu of a rinse, films may be mechanically stripped of excess sanitizing solution.

For a fine mist or vapor application, no rinse of treatment solution is required: (1) solution application does not exceed 0.0175 mL treatment solution per ounce container capacity; (2) treatment solution has not been recycled; and (3) no treatment solution with a concentration of higher than 4000 ppm peracetic acid has been added to the treatment solution reservoir.

This product may be used on food packaging as an aseptic packaging antimicrobial rinse in food packaging processing operation 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.

**Food Processing Equipment**

This product may be used to achieve commercial sterility of non-porous food manufacturing, packaging and filling equipment.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent may be used as a manufacturing, filling (including rotary fillers) and packaging equipment.

1. Remove gross soil particles from equipment surfaces.
2. Clean surfaces thoroughly.
3. Rinse thoroughly with potable water.
4. Apply 4000 ppm peroxyacetic acid at a minimum temperature of 65 °C.
5. Use immersion, coarse spray or circulation techniques to apply VigorOx<sup>®</sup> SP-15 Antimicrobial Agent. Automated application by fine mist or vapor deposition may be used within enclosed spaces.
6. Allow contact time of at least 20 seconds.
7. Allow to drain dry.
8. A final rinse with sterile water is optional

This product may be used on equipment used in aseptic packaging antimicrobial rinse in food processing operation 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.

**Foam Sanitization**

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent can be applied as a foam for sanitization of previously cleaned, hard, non-porous food-contact surfaces and general environmental (non-food contact) hard, non-porous surfaces such as floors, walls, ceilings, drains and boots. Foam applications can be used where penetration and retention of product for required times is difficult to achieve. Examples include operating conveyor belts, and vertical or uneven surfaces.

1. Prepare a dilute VigorOx<sup>®</sup> SP-15 Antimicrobial Agent solution by adding 0.3 to 0.5 fluid ounces per 4.5 gallons potable water.
2. After preparing the VigorOx<sup>®</sup> SP-15 Antimicrobial Agent diluted solution, add 1 to 10 fluid ounces of HRS<sup>™</sup> or add 2 to 20 fluid ounces of HRS II per 4.5 gallons of diluted solution. After the HRS<sup>™</sup> or HRS<sup>™</sup> II is added, adjust the total solution volume to 5 gallons. HRS<sup>™</sup> and HRS<sup>™</sup> II are the only approved foam-generating additives for use with VigorOx<sup>®</sup> SP-15 Antimicrobial Agent.
3. Apply the sanitizing solution as a foam using commercially available foam generating equipment. Allow foam to contact surfaces at least one (1) minute. For foot bath application, allow foam to remain on the boot surface for one minute upon exiting the bath.
4. Drain items and/or surfaces thoroughly.

**Sanitization of Non-porous Food Contact Surfaces**

For use in circulation cleaning and institutional/industrial sanitizing of previously cleaned non-porous food contact surfaces and equipment, such as pipelines, tanks, vats, fillers, evaporators, pasteurizers, and aseptic equipment in:

- Dairies, Wineries, Breweries and Beverage Plants
- Meat and Poultry Processing/Packaging Plants
- Milk and Dairy Products Processing/Packing Plants
- Seafood and Produce Processing/Packing Plants
- Food Processing/Packing Plants
- Egg Processing/Packing Equipment Surfaces
- Eating Establishments, and in
- Final Sanitizing Bottle Rinse

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is an effective sanitizer against *Staphylococcus aureus*, *Escherichia coli*, *Listeria monocytogenes* and *Salmonella typhimurium*.

Clean equipment immediately after use:

1. Remove gross particulate matter with a warm water flush.
2. Wash equipment with detergent or cleaning solution.
3. Rinse equipment with potable water.
4. Prepare VigorOx<sup>®</sup> SP-15 Antimicrobial Agent solution by adding 0.31 to 0.45 fluid ounces to 5 gallons potable water. This provides 85 to 123 ppm peroxyacetic acid and 57 to 82 ppm of hydrogen peroxide.
5. Fill closed systems with diluted sanitizer solution for a contact time of one (1) minute.

ACCEPTED with COMMENTS in EPA Letter Dated NOV 13 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended by the FIFRA Act of 1992, registration of this product is required.

65402-3

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6. If sanitizing against *Listeria monocytogenes* use 0.4 to 0.45 fluid ounces (109 to 123 ppm peroxyacetic acid and 73 to 82 ppm hydrogen peroxide) of product to 5 gallons of potable water.
7. For open or not completely closed systems, use a coarse spray, mop/wipe or flood technique to apply the solution to the surface for a contact time of at least one (1) minute. Allow surfaces to drain thoroughly before resuming operation.

VigorOx® SP-15 Antimicrobial Agent may be mixed with the non-foaming agent, Peradigm™ and applied at room temperature or at a minimum of 25 °C.

1. Mix 0.5 fluid ounce VigorOx® SP-15 Antimicrobial Agent with Peradigm in 4.5 gallons of water.
2. Add a maximum of 43 fluid ounces of Peradigm to the dilute solution, and bring total volume to 5 gallons. This provides 125 ppm peroxyacetic acid and 85 ppm hydrogen peroxide.
3. Apply solution, allowing a minimum contact time of 30 seconds.
4. Rinse with sterile or potable water.

**Eating Establishment Sanitizing**

VigorOx® SP-15 Antimicrobial Agent is an effective sanitizer against *Staphylococcus aureus*, *Escherichia coli*, *Listeria monocytogenes* and *Salmonella typhimurium*.

1. Scrape/prewash plates, utensils, cups, glasses, etc. whenever possible.
2. Wash all items with a detergent.
3. Rinse thoroughly with potable water.
4. Prepare VigorOx® SP-15 Antimicrobial Agent solution as follows: Add 0.31 to 0.45 fluid ounces of the product to 5 gallons of potable water. This will provide 85 to 123 ppm peroxyacetic acid and 57 to 82 ppm of hydrogen peroxide.
5. Immerse all items for at least one (1) minute or for a longer contact time if specified by the local governing sanitizing code.
6. If sanitizing against *Listeria monocytogenes* use 0.4 to 0.45 fluid ounces (109 to 123 ppm peroxyacetic acid and 73 to 82 ppm hydrogen peroxide) of product to 5 gallons of potable water.
7. Place all sanitized items on a rack or drainboard to drain adequately. Air dry if items will not be reused immediately.

**Sanitizing Tableware**

For sanitizing tableware in low to ambient temperature warewashing machines, inject the diluted VigorOx® SP-15 Antimicrobial Agent solution (0.31 to 0.45 fluid ounces of the product to 5 gallons of potable water) into the final-rinse water. This provides 85 to 123 ppm peroxyacetic acid and 57 to 82 ppm of hydrogen peroxide. Allow treated materials to drain adequately. Air dry if items will not be reused immediately.

**Final Sanitizing Bottle Rinse**

VigorOx® SP-15 Antimicrobial Agent may be used as a final sanitizing rinse for plastic, glass or metal returnable and non-returnable bottles/cans.

1. Wash bottles with detergent or cleaning solution and rinse with potable water.
2. Rinse bottles/cans with a solution prepared by mixing 0.31 to 0.45 fluid ounces of VigorOx™ SP-15 Antimicrobial Agent to 5 gallons of potable water. This provides 85 to 123 ppm peroxyacetic acid and 57 to 82 ppm of hydrogen peroxide. Allow to drain dry.

**Sanitization of Hatching Eggs**

1. Prepare a dilute solution by adding 0.31 to 0.45 fluid ounces of VigorOx® SP-15 Antimicrobial Agent to 5 gallons of potable water. This provides 85 to 123 ppm peroxyacetic acid and 57 to 82 ppm of hydrogen peroxide.
2. Apply dilute solution as eggs are gathered or prior to setting as a coarse spray or flood so as to lightly wet all egg shell surfaces.
3. Allow to drain dry.

**Sanitization of Conveyors, Peelers, Slicers, and Saws for Meat, Poultry, Seafood, Fruits, and Vegetables**

VigorOx® SP-15 Antimicrobial Agent is an effective sanitizer against *Staphylococcus aureus*, *Escherichia coli*, *Salmonella typhimurium* and *Listeria monocytogenes*.

For use in the washing, rinsing and sanitizing of conveyor equipment, peelers, collators, slicers, saws etc.

1. Remove all products from equipment unless treating only the return portion of a conveyor.
2. Prepare VigorOx® SP-15 Antimicrobial Agent solution by adding 0.31 to 0.45 fluid ounces to 5 gallons of potable water. This provides 85 to 123 ppm peroxyacetic acid and 57 to 82 ppm of hydrogen peroxide.
3. Apply sanitizer solution to the return portion of the conveyor or to the equipment using a coarse spray or other means of wetting the surfaces. Control the volume of solution so as to permit maximum drainage and to prevent puddles. The conveyor surface may still be damp when food contact occurs.
4. If sanitizing against *Listeria monocytogenes* use 0.4 to 0.45 fluid ounces (109 to 123 ppm peroxyacetic acid and 73 to 82 ppm hydrogen peroxide) of product to 5 gallons of potable water.
5. Allow equipment to drain adequately before reusing; a dry surface is not required.

**Surfaces Treated to Control the Spread of Citrus Canker**

VigorOx® SP-15 Antimicrobial Agent can be used to control the spread of citrus canker between inanimate surfaces and inanimate surfaces to plants. This product is for sanitizing surfaces such as packinghouse conveyers and harvesting equipment and containers. This product is not for treatment of infected plants.

**Packinghouse Sanitization**

VigorOx® SP-15 Antimicrobial Agent is an effective sanitizer against microorganisms such as *Xanthomonas campestris (axonopodis)* pathovars citrumelo (citrus canker surrogate) and *Aspergillus versicolor*, as well as *Staphylococcus aureus*, *Escherichia coli*, and *Salmonella typhimurium*.

1. Remove gross contamination with a cleaner or other suitable detergent and rinse with potable water.
2. Use VigorOx® SP-15 Antimicrobial Agent at a dilution of 3.1 fluid ounces per 50 gallons of water (85 ppm peroxyacetic acid and 57 ppm hydrogen peroxide) as a general sanitizing coarse spray to reduce bacterial and fungal contamination of walls, floors, conveyers and harvesting containers.
3. Allow sanitizer to contact surface for at least one (1) minute.
4. Allow to air dry, do not rinse.

**Field Equipment Sanitization**

VigorOx® SP-15 Antimicrobial Agent may be used to sanitize harvest equipment such as pickers, trailers, trucks (including truck body parts and tires), bins, packing crates, ladders, power tools, hand tools, gloves, rubber boots, pruning shears or other equipment that may transfer *Xanthomonas campestris (axonopodis)* pathovars citrumelo (citrus canker surrogate). This product can also be used to sanitize surfaces contaminated with *E. coli*, *Salmonella typhimurium*, and *S. aureus*.

1. Before sanitization, move the field equipment into an area with an impervious surface and with controlled drainage. Ensure that no sanitization solution will be released into the environment.
2. Remove gross contamination with a cleaner or other suitable detergent and rinse with water.
3. Use VigorOx® SP-15 Antimicrobial Agent at a dilution of 3.1 to 5.0 fluid oz per 50 gallons of water (85 to 135 ppm peroxyacetic acid and 57 to 90 ppm hydrogen peroxide) as a general sanitizing coarse spray.
4. Allow sanitizer to contact surface for at least one (1) minute.
5. Allow to air dry, do not rinse.

**Fogging**

VigorOx® SP-15 Antimicrobial Agent is for sanitizing hard room surfaces as an adjunct to acceptable manual cleaning and disinfecting of room surfaces.

1. Prior to fogging, remove or carefully protect all food products and packaging materials.
2. Ensure room is properly ventilated. Vacate all personnel from the room during fogging and for a minimum of 2 hours after fogging. Ensure there is no strong odor, characteristic of acetic acid, before having personnel return to work area.
3. Fog areas using one quart per 1000 cu. ft. of room area with a 0.1% VigorOx® SP-15 Antimicrobial Agent solution.
4. Allow surfaces to drain thoroughly before operations are resumed.

ACCEPTED FOR COMMENTS  
NOV 13 2010

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended... registered under Reg. No. 171072

## Surface Disinfection

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent is an effective one-step cleaner and disinfectant against gram positive and negative bacteria (vegetative forms) such as *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*. It is effective in hard water (up to 400 ppm as calcium carbonate equivalent), and in the presence of moderate organic soil. It may be used in general commercial and medical environments to clean, disinfect, and deodorize inanimate surfaces, such as:

- Floors, walls, and other non-porous surfaces such as tables, chairs, counter tops, garbage cans/bins, bathroom fixtures, sinks, bed frames, shelves, racks, carts, refrigerators, coolers, glazed tile, linoleum, vinyl, sealed asphalt, glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel or glass.
- Areas of use in hospitals, surgical and obstetrical suites; operating tables, housekeeping services; physical therapy departments; nursing homes, health care facilities, autopsy facilities, pharmaceutical and chemical processing facilities and equipment.
- Schools, colleges, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments.
- Animal hospitals, veterinary clinics, animal life science laboratories, kennels, kennel runs, cages, feeding and watering equipment, pet shops, zoos, pet animal quarters, poultry premises, trucks, hatcheries, and live stock quarters.

Prepare VigorOx<sup>®</sup> SP-15 Antimicrobial Agent disinfecting solution by adding 1.1 to 9.5 fluid ounces of the product to 5 gallons of potable water. This will provide 300 to 2600 ppm peroxyacetic acid and 200 to 1730 ppm hydrogen peroxide. If surfaces are moderately soiled, the disinfection solution may be used without a pre-cleaning step. For grossly soiled surfaces, remove filth from surfaces to be disinfected by cleaning with a detergent or suitable cleaning product. Rinse with clean water. To disinfect, apply VigorOx<sup>®</sup> SP-15 Antimicrobial Agent by wiping, mopping, or as a coarse spray. Allow to soak for at least 10 minutes, then air dry.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent may be mixed with the non-foaming agent, Peradigm<sup>™</sup>. Preclean surfaces prior to disinfection.

1. Prepare a diluted solution of VigorOx<sup>®</sup> SP-15 Antimicrobial Agent by adding a minimum of 1.0 fluid ounce to 4.5 gallons of water.
2. Add a maximum of 43 fluid ounces of Peradigm to the dilute solution, and bring total volume to 5 gallons.
3. Apply solution as previously described, allowing a minimum contact time of 10 minutes.

## Antimicrobial Rinse of Precleaned or New Returnable or Non-Returnable Containers

To reduce the number of nonpathogenic beverage spoilage organisms such as *Aspergillus versicolor*, *Byssoschlamys fulva*, *Pediococcus damnosus*, *Lactobacillus buchneri*, and *Saccharomyces cerevisiae*, use up to 10 fluid ounces of product per 5 gallons of water. This provides 2700 ppm peroxyacetic acid and 1800 ppm hydrogen peroxide. After applying the antimicrobial rinse, allow containers to drain thoroughly. Optional rinse with sterile or potable water.

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent may be mixed with the non-foaming agent, Peradigm<sup>™</sup> and applied at room temperature or at a minimum of 25 °C.

1. Mix a minimum of 0.5 fluid ounce VigorOx<sup>®</sup> SP-15 Antimicrobial Agent with Peradigm in 4.5 gallons of water.
2. Add a maximum of 43 fluid ounces of Peradigm to the dilute solution, and bring total volume to 5 gallons. This provides 125 ppm peroxyacetic acid and 85 ppm hydrogen peroxide.
3. Apply solution, allowing a minimum contact time of 30 seconds.
4. Rinse with sterile or potable water.

## For Porous and Non-porous Hard Surface Sterilization

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent may be used to sterilize both porous and non-porous hard surfaces in institutions, manufacturing, food processing or other non-medical facilities where sterilization is required. It is effective in the presence of 400 ppm hard water (measured as calcium carbonate equivalent) and moderate organic soil (tested as 5% serum).

1. Remove gross filth with a suitable detergent if present. Rinse with clean water.
2. Mix 2.5 fluid ounces VigorOx<sup>®</sup> SP-15 Antimicrobial Agent per gallon of clean water. This provides 3400 ppm of peroxyacetic acid and 2240 ppm of hydrogen peroxide.
3. Spray, sponge or flood to wet all surfaces thoroughly. Solution must remain in contact with surface for 6 hours. Reapply solution to surfaces as necessary to maintain wet conditions.
4. Rinse food-contact surfaces with a sterile or potable water rinse, followed by application of a sanitizing solution of VigorOx<sup>®</sup> SP-15 Antimicrobial Agent.
5. Do not re-use solution; prepare new solution each time.

This product is not to be used as a terminal sterilant/high level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may not be used to preclean or decontaminate any medical device.

## For Disinfection of Sewage and Wastewater Effluents in Treatment Plants

Use VigorOx<sup>®</sup> SP-15 Antimicrobial Agent to treat sewage and wastewater effluent related to public and private wastewater treatment plants. VigorOx SP-15 Antimicrobial Agent can be applied directly to the effluent or may be used with an appropriate activator such as hydrogen peroxide or other technology. VigorOx<sup>®</sup> SP-15 Antimicrobial Agent may be applied to effluent water discharged from trickle bed or percolating fluidized bed filters. The application rate for individual facilities will depend on the degree of bioloading of the effluent stream to be discharged and the local microbial discharge limit. Adjust application rate to meet the need of the individual facility.

1. Add VigorOx<sup>®</sup> SP-15 Antimicrobial Agent to effluent water at a concentration of 0.5 ppm to 15 ppm. Allow contact time of approximately 15 to 60 minutes.
2. The maximum amount of peracetic acid that can be discharged from the treatment facility is 1 ppm. Use an appropriate peracetic acid test kit analyzer to ensure that this level is not exceeded. Contact your FMC representative for assistance establishing treatment regimes.

## For Reducing Pathogenic Foodborne Bacteria in Processing Waters for Fruits and Vegetables

VigorOx<sup>®</sup> SP-15 Antimicrobial Agent can be used for reducing (in 90 seconds) 99.9% of pathogenic food borne bacteria (*Escherichia coli*, *Salmonella enterica*, and *Listeria monocytogenes*) in processing waters for fruits and vegetables.

1. Ensure the solution is thoroughly mixed.
2. Add VigorOx<sup>®</sup> SP-15 Antimicrobial Agent at a dilution of 0.54 fluid ounce per 16 gallon of water. This provides approximately 45 ppm peroxyacetic acid and 30 ppm hydrogen peroxide.
3. Allow the solution to circulate at least 45 seconds before adding or treating raw, fresh-cut or processed fruits and vegetables.
4. Add concentrate as needed to maintain a minimum product concentration of 45 ppm peroxyacetic acid.
5. Prepare fresh process water daily. Do not reuse water that is badly fouled.

## For Treatment of Processing Waters to Control Growth of Non-Public Health Microorganisms that Can Cause Spoilage of Fresh-Cut, Post-Harvest or Processed Fruits and Vegetables

1. Ensure the solution is thoroughly mixed.
2. Add VigorOx<sup>®</sup> SP-15 Antimicrobial Agent at a dilution of 0.1 fluid oz. to 1.0 fluid oz. per 16 gallons of water. This provides 5 to 85 ppm peroxyacetic acid and 4 to 57 ppm hydrogen peroxide.
3. Allow the solution to circulate at least 45 seconds before adding or treating raw, fresh-cut or processed fruits and vegetables.
4. Add concentrate as needed to maintain a concentration of at least 5 ppm peroxyacetic acid and 4 ppm hydrogen peroxide.
5. Prepare fresh process water daily. Do not reuse water that is badly fouled.

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the purposes of registration under the Act, No. 67762-2

9099

**For Treatment of Processed Fruit and Vegetable Surfaces and Process Water to Control Growth of Non-Public Health Microorganisms that Can Cause Spoilage**

1. Add VigorOx® SP-15 Antimicrobial Agent at a dilution of 1.5 fluid ounces per 25 gallons of water. Ensure that the solution is thoroughly mixed. This provides 80 ppm of peroxyacetic acid and 50 ppm of hydrogen peroxide.
2. Apply the prepared solution as a spray or dip. Allow a minimum contact time of 45 seconds. No rinse following application is required. This use complies with the requirements at 21 C.F.R. 173.315 (a) (5). A potable water rinse is not required following application of the diluted solution.

**For Treatment of Raw, Unprocessed Fruit and Vegetable Surfaces**

VigorOx® SP-15 Antimicrobial Agent can be applied as a dip or spray to control the growth of non-public health microorganisms such as *Xanthomonas campestris (axonopodis)* pathovars citrumelo (citrus canker surrogate) and *Aspergillus versicolor*, blue mold (*Penicillium* species), green mold (*Penicillium* species) and stem-end rot (*Geotrichium*) that may cause decay and/or spoilage on raw, post-harvest fruits and vegetables during the washing process. This product can be applied during physical cleaning processes, including at the roller spreader, washer manifold, dip tank, on the brushes or elsewhere in the washing process prior to, simultaneously with or after detergent wash.

1. Prepare treatment solution by adding 1.0 fluid ounce per 16 gallons of potable water. This will provide 85 ppm peroxyacetic acid and 57 ppm hydrogen peroxide.
2. Apply the diluted sanitizer solution using a coarse spray directed at the fruits or vegetables, or by soaking the fruits or vegetables in the solution. Allow a contact time of at least 45 seconds.
3. The treated produce can be drain dried without a potable water rinse.
4. Do not reuse solution after treatment.

VigorOx® SP-15 Antimicrobial Agent can be used on the following raw and post-harvest fruits and vegetables

- Root and tuber vegetables such as carrots and potatoes
- Bulb vegetables such as onions, garlic and shallots
- Leafy vegetables such as lettuce and spinach
- Brassica leafy vegetables such as broccoli, cabbage and cauliflower
- Legumes such as beans, peas and lentils
- Fruiting vegetables such peppers, tomato, and eggplant
- Cucurbits such cucumbers, melons, squash, and pumpkins
- Citrus fruits such oranges, lemons, limes, and grapefruit
- Pome fruits, apples and pears
- Stone Fruits such as cherries, peaches, nectarine, and plum
- Small fruits and berries: blackberries, blueberries, red and black raspberries
- Tree nuts such almond, brazil, filbert, cashew, and pecan
- Cereal grains such corn, barley, oats, rice, and wheat
- Herbs and spices such basil, chives, coriander, and dill
- Miscellaneous fruits and vegetables such as asparagus, avocado, artichoke, banana, cranberry, fig, grapes, kiwifruit, mango, mushroom, okra, papaya, peanut, pineapple, strawberry and water chestnut

**Agricultural and Horticultural Uses**

A Restricted-Entry-Interval of zero (0) hours is required for VigorOx® SP-15 Antimicrobial Agent in agricultural or horticultural uses. This product should not be mixed or combined with any pesticides or fertilizers. Upon soil contact , the diluted product decomposes rapidly to oxygen, carbon dioxide and water. This product may be harmful to fish if exposed on a continuous basis at concentrations greater than 1 ppm of active peracetic acid. Meter VigorOx® SP-15 Antimicrobial Agent into pressurized pipes using a plastic or stainless steel injection/backflow device installed upstream from the equipment to ensure thorough mixing prior to application. For open bodies of water, allow adequate mixing prior to product flow entering any body of water. If open pouring of this product is required , pour product close to the surface of the water as possible to reduce odor and exposure.

**Treatment of Agricultural and Irrigation Water Systems**

Use VigorOx® SP-15 Antimicrobial Agent to control sulfides, odor, slime, and algae in sand filters, humidification systems, storage tanks, ponds, reservoirs, canals. Apply VigorOx® SP-15 Antimicrobial Agent at 15 to 75 fluid ounces per 10,000 gallons of water. This provides 2 ppm to 10 ppm peroxyacetic acid. Repeat dose as necessary to maintain control. For prevention of algae, some systems may require continuous low level dosing during warm, sunny periods (2 ppm to 5 ppm peroxyacetic acid).

**Drip Irrigation Systems**

To clean slime and algae from drip system filters, tapes and emitters, meter VigorOx® SP-15 Antimicrobial Agent at 7.5 to 15 fluid ounces per 1000 gallons. This provides 10 ppm to 20 ppm peroxyacetic acid. Use this product at the recommended dose for a minimum of 30 minutes during normal irrigation cycles. Upon irrigation cycle completion, discontinue use and flush the lines.

**For Sanitization and Disinfection of Laundry in Commercial and Institutional and Industrial Operations**

Use VigorOx® SP-15 Antimicrobial Agent in commercial and Institutional and Industrial including Hospitality laundry operations for control of microorganisms including *Klebsiella pneumonia*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *E. coli* and other coliforms.

For sanitization to control *Klebsiella pneumonia*:

1. Add 2.3 fluid ounces VigorOx® SP-15 Antimicrobial Agent per 100 pounds of dry laundry - assumes 5 parts water to 1 part dry laundry based on 100 lbs. of dry laundry.
2. Inject VigorOx® SP-15 Antimicrobial Agent into the sanitizing rinse step at 2.3 fluid ounces per 60 gallons of water applied. VigorOx® SP-15 Antimicrobial Agent is effective in water up to 400 ppm of water hardness. Treat laundry for a minimum of 5 minutes at a minimum of 18 °C. Following sanitization, laundry may be rinsed with water that may include a softener, starch, odor neutralizer, fragrance, soil release agent, and/or fluid repellent.

For disinfection:

1. Add 13.6 fluid ounces VigorOx® SP-15 Antimicrobial Agent per 100 pounds of dry laundry - assumes 5 parts water to 1 part dry laundry based on 100 lbs. of dry laundry.
2. Inject VigorOx® SP-15 Antimicrobial Agent into the disinfecting rinse step at 13.6 fluid ounces per 60 gallons of water applied. VigorOx® SP-15 Antimicrobial Agent is effective in water up to 400 ppm of water hardness. Treat laundry for a minimum of 15 minutes at a minimum of 20 °C. Following disinfection, laundry may be rinsed with water that may include a softener, starch, odor neutralizer, fragrance, soil release agent, and/or fluid repellent.

**Note: May cause bleaching of treated surfaces; test commodity if unsure.**

**Note: Before using VigorOx® SP-15 Antimicrobial Agent to sanitize metal surfaces, it is recommended that the diluted solution be tested on a small area to determine compatibility.**

In all applications always prepare a new solution daily to ensure effectiveness. Do not re-use solutions. Dispose of unused solution.

**EMERGENCY TELEPHONE NUMBERS  
(24 HOURS)**  
**MEDICAL: COLLECT 303-595-9048**  
**TRANSPORTATION: 800-424-9300**  
**OTHER: COLLECT 716-879-0400**

ACCEPTED  
 with COMMENTS  
 in EPA Label Draft: REV 061710  
**NOV 13 2010**

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) of 1972, this product is registered under EPA Reg. No. 101-103-01