UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

65402-6

07/31/2002

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Frank Caropreso Manager Regulatory Affairs FMC Corporation, Active Oxidants Division P.O. Box 8 Princeton, NJ 08543

Subject:

VigorOx Citrus XA EPA Reg. No. 65402-6

Your Re-Submission Dated 5/13/2002

The submission referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, which responds to the EPA letter dated 4/18/02 by providing a revised master label (5/8/02 version), is acceptable with the following comments.

This accepted label version supercedes all prior stamped label versions in commerce which become invalid, as per EPA regulation, after 18 months of the date of this letter. With your next scheduled amendment for this product involving a label change, you must make the following minor revisions:

- 1. Increase the typesize of the signal word "DANGER" to that required in the EPA "Label Review Manual" for your label size. The signal word must be larger than the "Keep Out of Reach of Children" statement.
- 2. In the section "Sanitizing Non-Porous Food Contact Surfaces", make the last sentence in instruction #7 (ie., "Allow surfaces to drain thoroughly before resuming operations"), as a new instruction #8. This will clarify that it is applicable to all uses in this section.

A stamped copy of the label (accepted with comments) is attached for your records.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

	·		Sincerely, Marshall Swindell, Product Manager Team Regulatory Management	,
· · · · · · · · · · · · · · · · · · ·		CONCURRENCES	Antimicrobials Division	
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PA Form 1320-1A (1/90)		Printed on Recycled Pap	er	OFFICIAL FILE COPY

VigorOx® Citrus XA

EPA Registration No. 65402-6 EPA Est. No. 00279-NY-003

VigorOx® Citrus XA 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® Citrus XA 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)

VigorOx® Citrus XA is for sanitizing surfaces such as packinghouse conveyors, harvesting equipment and containers. It is effective against Plant pathogens such as Xanthomonas campestris (axonopodis) athovars citrumelo (citrus canker surrogate).

VigorOx® Citrus XA is for sanitizing of inanimate, non-food contact surfaces (general environmental surfaces)

VigorOx® Citrus XA is for use in the disinfection of hard surfaces in general commercial and medical environments such as:

- Hospitals, Health Care Facilities, Veterinary Hospital/Clinics, Animal Life Science Labs, Pharmaceutical Facilities and Equipment
- Schools, Colleges, Recreational Facilities, Office Buildings
- Livestock Premises, Poultry Premises, Poultry Hatcheries, Animal **Housing Facilities**
- Retail and Wholesale Establishments
- **Bathroom Premises**

VigorOx® Citrus XA is for use as a coarse spray for surfaces to be sanitized or disinfected.

VigorOx® Citrus XA is for use in fogging applications as an adjunct to acceptable manual cleaning and disinfecting of room surfaces.

JigorOx® Citrus XA is for use in the sanitization of ultra filtration and reverse osmosis (RO) membranes and their associated distribution systems.

KEEP OUT OF REACH OF CHILDREN DANGER

See side panel for additional precautionary statements

FMC Corporation Active Oxidants Division 1735 Market Street Philadelphia Pennsylvania 19103 JUL 3 1 2002

Under the Federal Insecticide. Pungicide, and Rodenticide Act as amended, for the pesticide,

For Industrial Use Only registered under EPA Reg. No.

Peroxyacetic Acid...... 5.1% Active Ingredients: Hydrogen Peroxide.......21.7% Inert Ingredients:100.0% Total

Precautionary Statements Hazards to Humans and Domestic Animals

DANGER - Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. May be fatal if absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses), clothing and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse

Physical or Chemical Hazards - Strong oxidizing agent. Mix only with water. VigorOx® Citrus XA 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 life. 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
 - · 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.

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 be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

FMC and VigorOx® are trademarks of FMC Corporation



Storage and Disposal Pesticide Storage

NEVER RETURN VigorOx® CITRUS XA 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 a 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 water. Undiluted material should not enter confined spaces.

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® Citrus XA, 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

Empty drums are not returnable to FMC unless special arrangements have been made. Triple rinse drums with water. Dispose of drums in accordance with local, state, and Federal regulations. **DO NOT REUSE**.

Directions for Use

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

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

- · Dairies, Wineries, Brewerles 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
- Final Sanitizing Bottle Rinse

Sanitizing Non-Porous Food Contact Surfaces

VigorOx® Citrus XA is an effective sanitizer against Staphylococcus aureus, Escherichia coli, and Salmonella typhimurium.

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

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Clean equipment immediately after use:

- I. Remove gross particulate matter with a warm water flush.
- 2. Wash equipment with detergent or cleaning solution.
- 3. Rinse equipment with potable water.
- Prepare VigorOx® Citrus XA solution by adding 1.0 to 1.7 ounces to 5 gallons potable water. This provides 85 to 150 ppm peroxyacetic acid and 375 to 630 ppm hydrogen peroxide.
- Fill closed systems with diluted sanitizer solution and allow a contact time of one (1) minute. If sanitizing at temperatures of 5°C (40°F) or lower, use at least 1.6 ounces of product to 5 gallons of potable water.
- If sanitizing against Listeria monocytogenes, use 1.2 to 1.7 ounces of this product to 5 gallons of potable water. This will provide 100 to 150 ppm of peroxyacetic acid and 375 to 630 ppm of hydrogen peroxide.
- For open or not completely closed systems, use a coarse spray, mop/wipe or flood technique to apply the solution to the surface for at least one (1) minute. Allow surfaces to drain thoroughly before resuming operation.

Eating Establishment Sanitizing

VigorOx® Citrus XA is an effective sanitizer against Staphylococcus aureus, Escherichia coli, and Salmonella typhimurium.

- Scrape/prewash plates, utensils, cups, glasses, etc. whenever possible.
- 2. Wash all items with a detergent.
- 3. Rinse thoroughly with potable water.
- Prepare VigorOx® Citrus XA solution as follows:
 Add 1.0 to 1.7 ounces of the product to 5 gallons of potable water.
 This will provide 85 to 150 ppm peroxyacetic acid and 375 to 630 ppm hydrogen peroxide.
- Immerse all Items for at least one (1) minute or for a contact time as specified by the local governing sanitizing code.
- If sanitizing against Listeria monocytogenes, use 1.2 to 1.7 ounces of this product to 5 gallons of potable water. This will provide 100 to 150 ppm of peroxyacetic acid and 375 to 630 ppm of hydrogen peroxide.
- Place all sanitized Items on a rack or drainboard to drain adequately, air dry if items will not be re-used immediately.

Sanitizing Tableware

For sanitizing tableware in low to ambient temperature warewashing machines, inject the diluted VigorOx® Citrus XA solution (1.0 to 1.7 fluid ounces of the product to 5 gallons of potable water) into the final rinse water. Allow treated materials to drain adequately; air dry if items will not be re-used immediately.

Final Sanitizing Bottle Rinse

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

- Wash bottles with detergent or cleaning solution and rinse with potable water.
- Rinse bottles/cans with a solution prepared by mixing 1.0 to 1.7 ounces of VigorOx® Citrus XA to 5 gallons of potable water. Allow to drain dry.

Sanitization of Hatching Eggs

- Prepare a dilute solution by adding 1.0 to 1.7 ounces of VigorOx® Citrus XA to 5 gallons of potable water.
- 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® Citrus XA is an effective sanitizer against Staphylococcus aureus, Escherichia coli, and Salmonella typhimurium.

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

- Remove all products from equipment unless treating only the return portion of a conveyor.
- Prepare VigorOx® Citrus XA solution by adding 1.0 to 1.7 ounces to 5 gallons of potable water.
- Apply sanitizer solution to the return portion of the conveyor or to tequipment using a coarse spray or other means of wetting the surfaces, (treat for at least one (1) minute). Control the volume of solution so as to permit maximum drainage and prevent puddles. The converyor may still be damp when food contact occurs.
- If sanitizing against Listeria monocytogenes, use 1.2 to 1.7 ounces of this product to 5 gallons of potable water.
- Allow equipment to drain adequately before reusing; a dry surface is not required.

General Environmental Surfaces Sanitization (Non-Food Contact)

VigorOx® Citrus XA is an effective inanimate non-food contact surface sanitizer against Staphylococcus aureus, Klebsiella pneumoniae, and Saccharomyces cerevisiae.

Sanitization of surfaces such as floors, walls, tables, chairs, benches, rains etc., can be accomplished using the following procedures:

- Remove gross filth with a cleaner or other suitable detergent.
- Add 1 oz. of VigorOx™ Citrus XA to 16 gallons of potable water to prepare a solution containing 27 ppm of peroxyacetic acid and 115 ppm of hydrogen peroxide.
- Soak items in/with diluted solution using mop/wipe, coarse spray or flood techniques and allow contact for at least 5 minutes.
- 4. Allow items and/or surfaces to drain adequately or air dry.

Surfaces treated to control the spread of Citrus Canker

VigorOx® Citrus XA 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 conveyors and harvesting equipment and containers. This product is not for treatment of infected plants.

Packinghouse Sanitization

VigorOx® Citrus XA is an effective sanitizer against microorganisms such as Xanthomonas campestris (axonopodis) pathovars citrumelo (citrus canker surrogate), and Staphyloccoccus aureus, Escherichia coli and Salmonella typhimurium.

Remove gross contamination with a cleaner or other suitable detergent and rinse with potable water.

- Use VigorOx® Citrus XA at a dilution of 9.7 to 15.5 fl oz per 50 gallons of water (85 to 135 ppm peroxyacetic acid and 360 to 575 ppm hydrogen peroxide) as a general sanitizing coarse spray to reduce bacterial and fungal contamination of walls, floors, conveyors and harvesting containers.
- 3. Allow sanitizer to contact surface for at least one (1) minute.
- Allow to air dry, do not rinse.

Field Equipment Sanitization

VigorOx® Citrus XA 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*.

- 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.
- Remove gross contamination with a cleaner or other suitable detergent and rinse with water.
- Use VigorOx® Citrus XA at a dilution of 9.7 to 15.5 fl oz per 50 gallons of water (85 to 135 ppm peroxyacetic acid and 360 to 575 ppm hydrogen peroxide) as a general sanitizing coarse spray.
- 4. Allow sanitizer to contact surface for at least one (1) minute.
- Allow to air dry. Do not rinse.

Fogging

VigorOx™ Citrus XA is for sanitizing hard room surfaces, as an adjunct to acceptable manual cleaning and disinfecting of room surfaces.

- Prior to fogging, remove or carefully protect all food products and packaging materials.
- 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.
- Fog areas using one quart per 1000 cu. ft. of room area with a 0.30% VigorOx® Citrus XA solution.
- 4. Allow surfaces to drain thoroughly before operations are resumed.

Surface Disinfection

VigorOx® Citrus XA is an effective disinfectant against gram positive and negative bacteria (vegetative forms) such as Staphylococcus aureus, Salmonella choleraesuis, Pseudomonas aeruginosa, and 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, tile, linoleum, vinyl, asphalt, 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® Citrus XA disinfecting solution by adding 3.2 to 30 oz. of the product to 5 gallons of potable water. This will provide 280 to 2600 ppm peroxyacetic acid and 1200 to 11,200 ppm hydrogen peroxide. Remove gross filth from surfaces to be disinfected by cleaning with a detergent or suitable cleaning product. Rinse with clean water. Apply VigorOx® Citrus XA solution by wiping, mopping, or as a coarse spray. Allow to soak for at least 10 minutes, then drain treated surfaces. Applications involving treatment of food contact surfaces, require a sterile or potable water rinse following disinfection.

Antimicrobial Rinse of Pre-Cleaned or New Returnable or Non-Returnable Containers

If non-pathogenic beverage spoilage organisms, (for example Aspergillus versicolor and Byssochlamys fulva), are present, use 7.0 to 30 fluid oz. of product per 5 gallons of water. This provides 600 to 2600 ppm peroxyacetic acid and 2550 to 11,200 ppm hydrogen peroxide. After applying antimicrobial rinse, allow containers to drain throughly, then rinse with sterile or potable water.

Disinfection and Deodorizing of Animal Housing Facilities, Poultry Premises, Coops, Trucks and Crates

- Remove all animals / poultry from the facilities / items / areas to be disinfected.
- Remove gross particulate, litter, droppings etc. with a warm water flush or by sweeping.
- Empty all troughs, racks, and other feeding and watering equipment.
- Wash all items thoroughly with detergent or cleaning solution and rinse with potable water.
- Prepare a disinfecting solution by adding 3.2 ounces of VigorOx® Citrus XA to 5 gallons of potable water. This provides 280 ppm of peroxyacetic acid and 1200 ppm of hydrogen peroxide.
- Before starting the treatment ensure that the work area is well ventilated
- Saturate surfaces with the diluted product for a period of at least 10 minutes.
- 8. Thoroughly scrub treated feed equipment i.e. With a foundation of the countries of the c
- Do not return animals / poultry or use equipment until solution has been completely absorbed or air dried.

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Poultry Hatchery Disinfection

- Remove remaining eggs and chicks, and all gross particulate and other hatching-related debris.
- Thoroughly wash all surfaces, with a recommended detergent or cleaning solution and then rinse with potable water.
- Prepare the disinfecting solution by adding 3.2 ounces of VigorOx® Citrus XA to 5 gallons of potable water.
- Before starting the treatment, ensure that the work area / room and any closed spaces are well ventilated.
- Apply the disinfecting solution with a mop, cloth, brush or coarse spray, keeping surfaces wet for 10 minutes.
- Air dry before re-introducing eggs.

Batch Sanitization of Ultra-Filtration and Reverse Osmosis (RO) Membranes

VigorOx® Citrus XA is for use in the sanitization of ultra filtration, medical and non-medical institutional/industrial reverse osmosis (RO) membranes and their associated distribution systems. VigorOx® Citrus XA is not for use in kidney dialysis reprocessing equipment.

This product has been shown to be an effective disinfectant when tested by AOAC and EPA methods. This product may not totally eliminate all vegetative microorganisms in reverse osmosis membranes and their associated piping systems due to their construction and/or assembly, but can be relied upon to reduce the number of microorganisms to acceptable levels when used as directed. Check with equipment manufacturer for membrane compatibility with VigorOx® citrus XA.

- Remove biological or organic fouling from the membrane or other parts of the system with an appropriate cleaner.
- 2. Flush the system with RO permeate or similar quality water.
- Remove mineral deposits with an acidic cleaner prior to sanitizing the membranes.
- 4. Flush the system with RO permeate or similar quality water.
- Prepare an appropriate volume of 1% solution of the product. This will provide 560 ppm of peroxyacetic acid and 2400 ppm hydrogen peroxide.
- Fill the entire water circuit to be sanitized with the dilute solution and allow the solution to reach a minimum of 20°C (69°F).
- Recirculate the dilute solution of VigorOx® Citrus XA for a minimum of 10 minutes.
- Allow membrane elements to soak in the solution for a minimum of 20 minutes.
- Rinse the RO system and test for residuals to ensure that there is less than 3 ppm per oxygen. Residuals can be reduced by diverting product water to drain.

Batch Sanitization of Piping Systems Associated with RO **14embranes**

Isolate incompatible equipment from piping system. This Includes activated carbon filters and ion exchange equipment. Turn off power to ultraviolet light units.

- Estimate total volume of water contained in the system (tanks, rinse stations and piping). Prepare an appropriate volume of 1.0 to 1.5% VigorOx® Citrus XA solution by adding 1.0 to 1.5 gallons of the product for every 100 gallons of solution prepared. Use RO permeate or similar quality water for dilution. This will provide 560 to 840 ppm peroxyacetic acid and 2250 to 3380 ppm hydrogen peroxide.
- Recirculate the dilute VigorOx® Citrus XA solution through the system for a minimum of 4 hours. Process usage valves should be opened and closed to expose internals to the VigorOx® Citrus XA solution.
- 4. Completely drain the system of dilute VigorOx® Citrus XA solution. Thoroughly rinse the system by filling with RO permeate or similar quality water and recirculate before drainage. Repeat the process until test for residuals indicates there is less then 3 ppm peroxygen.

Continuous/Intermittent Addition to Minimize the Accumulation of Biological Matter Between Intermittent Sanitizing Episodes in Piping Systems Associated with RO Membranes.

- 1. VigorOx® Citrus XA, as received or diluted, may be added continuously to the feed water stream, between system sanitizing episodes, to aid in minimizing the regrowth/ accumulation of biological matter. The peroxygen residual in the system which will be effective will vary with the design and usage characteristics of the system. Adjust the addition rate of VigorOx® Citrus XA or the solution and periodically monitor residual peroxygen so that the desired effect is obtained.
- For continuous addition do not exceed 20 ppm VigorOx® Citrus XA.
 This will give 1 ppm peroxyacetic acid and 4 ppm hydrogen peroxide.

 For intermittent feed do not exceed 2000 ppm VigorOx® Citrus XA.
 This will give 100 ppm peroxyacetic acid and 400 ppm hydrogen peroxide.

Note: Before using VigorOx® Citrus XA 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 sanitizing/disinfecting solution daily to ensure effectiveness. Do not reuse sanitizing/disinfecting solutions. Dispose of any unused sanitizing/disinfecting solution.

For more information see Material Safety Data Sheet

Master Citrus XA - EPA Revision 002 Label Effective Date: May 2002

ACCEPTED with COMMENTS in EPA Letter Dated:

JUL 3 1 2002

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