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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OCT 31 2000

FMC Corporation, Active Oxidants Division
Box 8
Princeton, NJ 08543

Attention: Frank E. Caropreso, Manager
Regulatory Affairs

Mail To: Elizabeth A. Heger
Keller and Heckman, LLP
1001 G. Street, N.W.
Washington, D.C. 20001

Subject: VigorOX Liquid Sanitizer and Disinfectant
EPA Registration No. 65402-1
Amendment Dated May 22, 2000 and
Letters Dated September 12, 2000 and October 22, 2000

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) and sec. 4 when the Agency requires all registrants of similar product to submit such data.

2. On the label under the heading "Sanitizing Non-Porous Food Contact Surfaces" delete the word "Listeria monocytogenes" from the paragraph beginning with VirorOx Liquid Sanitizer and Disinfectant is an effective sanitizer against.....Listeria monocytogenes".

3. On the label under the heading "Eating Establishment Sanitizing" delete the word "Listeria monocytogenes" from the paragraph beginning with VirorOx Liquid Sanitizer and Disinfectant is an effective sanitizer against.....Listeria monocytogenes".

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

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4. Change the heading "Statement of Practical Treatment" to read "First Aid".
5. Under the subheading "If inhaled:" revise the sentence Remove to fresh air" to Remove victim to fresh air".
6. Submit five (5) copies of final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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

If you have any questions concerning this letter, please contact Martha Terry at 703-308-6217.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7505C)

Enclosure

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VigorOx™ Liquid Sanitizer and Disinfectant

EPA Registration No. 65402-1
EPA Est. No. 00279-NY-003

VigorOx™ Liquid Sanitizer and Disinfectant 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™ Liquid Sanitizer and Disinfectant 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™ Liquid Sanitizer and Disinfectant is for sanitizing of inanimate, non-food contact surfaces, (general environmental surfaces)

VigorOx™ Liquid Sanitizer and Disinfectant 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™ Liquid Sanitizer and Disinfectant is for use as a coarse spray for surfaces to be sanitized or disinfected.

VigorOx™ Liquid Sanitizer and Disinfectant is for use in fogging applications as an adjunct to acceptable manual cleaning and disinfecting of room surfaces.

VigorOx™ Liquid Sanitizer and Disinfectant is for use in the sanitization of ultra filtration and reverse osmosis (RO) membranes and their associated distribution systems.

For Industrial Use Only

Active Ingredients:	Peroxyacetic Acid.....	5.1%
	Hydrogen Peroxide.....	21.7%
Inert Ingredients:	73.2%
Total	100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

ACCEPTED
with COMMENTS
in EPA Letter Dated:

See side panel for additional precautionary statements.

FMC Corporation

Active Oxidants Division

1735 Market Street

Philadelphia Pennsylvania 19103

OCT 31 2000
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
65402-1

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™ Liquid Sanitizer and Disinfectant 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.

Statement of Practical Treatment

If swallowed: Rinse mouth with water. Dilute by giving 1 or 2 glasses of water. Do not induce vomiting. See a physician.

If inhaled: Remove to fresh air. If breathing discomfort occurs, call a physician. If breathing has stopped, apply artificial respiration and see a physician.

If in eyes: Immediately flush with water for at least 15 minutes, lifting the upper and lower eyelids intermittently. See a physician.

If on skin: Immediately flush with plenty of water while removing contaminated clothing and/or shoes. Wash skin thoroughly with soap and water. See a physician. Wash contaminated shoes and clothing before reuse.

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

This product is not to be used as a terminal sterilant or 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 normal 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 pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

Storage and Disposal

Storage

NEVER RETURN VigorOx™ LIQUID SANITIZER AND DISINFECTANT 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 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™ Liquid Sanitizer and Disinfectant, 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

It 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 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
- Final Sanitizing Bottle Rinse

Sanitizing Non-Porous Food Contact Surfaces

VigorOx™ Liquid Sanitizer and Disinfectant is an effective sanitizer against *Staphylococcus aureus*, *Escherichia coli*, *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™ Liquid Sanitizer and Disinfectant solution by adding 1.0 to 1.9 ounces to 5 gallons potable water. This provides 85 to 165 ppm peroxyacetic acid and 375 to 700 ppm hydrogen peroxide.
5. Fill closed systems with diluted sanitizer solution at a temperature of 5°C (41°F) to 40°C (104°F) and a contact time of one (1) minute. If sanitizing at temperatures below 25°C, (77°F) use 1.6 to 30 ounces of product to 5 gallons of potable water.
6. If sanitizing against *Listeria monocytogenes*, use at least 1.2 ounces of this product to 5 gallons of potable water. This will provide 111 ppm of peroxyacetic acid and 473.6 ppm of hydrogen peroxide.
7. For open or not completely closed systems, use a coarse spray, mop/wipe or flood technique to apply the solution to the surface. Allow surface to drain thoroughly before resuming operation.
8. If non-pathogenic microorganisms such as *Bysschochlamys fulva* are present, use up to 30 oz. of product per 5 gallons of water. A solution of 30 oz. of product per 5 gallons of water provides 2800 ppm peroxyacetic acid and 11,200 ppm hydrogen peroxide.
9. When solutions exceeding 1.9 ounces of the product per 5 gallons of water are used, they must be followed with a sterile or potable water rinse.

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10. Water rinses must be followed by sanitization using 1.0 to 1.9 oz. of product per 5 gallons of water. Allow surfaces to drain thoroughly before resuming operation.

Eating Establishment Sanitizing

VigorOx™ Liquid Sanitizer and Disinfectant is an effective sanitizer against *Staphylococcus aureus*, *Escherichia coli*, *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™ Liquid Sanitizer and Disinfectant solution as follows:
Add 1.0 to 1.9 ounces of the product to 5 gallons of potable water. This will provide 85 to 165 ppm peroxyacetic acid and 375 to 700 ppm hydrogen peroxide.
5. Immerse all items for at least 2 minutes or for a contact time as specified by the local governing sanitizing code.
6. If sanitizing against *Listeria monocytogenes*, use at least 1.2 ounces of this product to 5 gallons of potable water. This will provide 100 ppm of peroxyacetic acid and 440 ppm of hydrogen peroxide.
7. Place all sanitized items on a rack or drainboard to air dry.

Sanitizing Tableware

For sanitizing tableware in low temperature warewashing machines, inject the diluted VigorOx™ Liquid Sanitizer and Disinfectant solution (1.6 to 1.9 ounces of the product to 5 gallons of potable water) into the final rinse water. At ambient temperatures, i.e., 25°C or higher, this product can be used at 1.0 ounce to 5 gallons of potable water. Allow treated materials to air dry.

Final Sanitizing Bottle Rinse

VigorOx™ Liquid Sanitizer and Disinfectant 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 1.0 to 1.9 ounces of VigorOx™ Liquid Sanitizer and Disinfectant to 5 gallons of potable water. Allow to drain dry.
3. If non-pathogenic microorganisms such as *Bysschochlamys fulva* are present, use up to 30 oz. of product per 5 gallons of water.
4. When solutions exceeding 1.9 oz. of product per 5 gallons of water are used, they must be followed with a sterile or potable water rinse.
5. Water rinses must be followed by sanitization using 1.0 to 1.9 oz. of product per 5 gallons of water. Allow to drain dry.

Sanitization of Hatching Eggs

1. Prepare a dilute solution by adding 1.0 to 1.9 ounces of VigorOx™ Liquid Sanitizer and Disinfectant to 5 gallons of potable water.
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 for Meat, Poultry, Seafood, Fruits, and Vegetables

VigorOx™ Liquid Sanitizer and Disinfectant is an effective sanitizer against *Staphylococcus aureus*, *Escherichia coli*, *Salmonella typhimurium*.

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

1. Remove all products from equipment.
2. Prepare VigorOx™ Liquid Sanitizer and Disinfectant solution by adding 1.0 to 1.9 ounces to 5 gallons of potable water.
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.
4. If sanitizing against *Listeria monocytogenes*, use at least 1.2 ounces of this product to 5 gallons of potable water.
5. Allow equipment to drain dry before reusing.

OCT. 31 2000

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 65402-1

General Environmental Surfaces Sanitization (Non-Food Contact)

VigorOx™ Liquid Sanitizer and Disinfectant is an effective inanimate non-food contact surface sanitizer against *Staphylococcus aureus*, *Klebsiella pneumoniae*, and *Saccharomyces cerevisiae*. Sanitation of surfaces such as floors, walls, tables, chairs, benches, drains etc., can be accomplished, using the following procedures:

1. Remove gross filth with a cleaner or other suitable detergent.
2. Add 1 oz. of VigorOx™ Liquid Sanitizer and Disinfectant to 16 gallons of potable water to prepare a solution containing 27 ppm of peroxyacetic acid and 115 ppm of hydrogen peroxide.
3. 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 air dry.

Sanitizing

VigorOx™ Liquid Sanitizer and Disinfectant is for use in the sanitization of ultra filtration and institutional/industrial use reverse osmosis membranes and their associated piping systems, and general commercial and medical environments. The product may be added continuously to the feed water stream to prevent the accumulation of biological matter between sanitization episodes. VigorOx™ Liquid Sanitizer and Disinfectant is not for use in kidney dialysis reprocessing equipment.

Surface Disinfection

VigorOx™ Liquid Sanitizer and Disinfectant 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™ Liquid Sanitizer and Disinfectant disinfecting solution by adding 3.2 to 30 oz. of the product to 5 gallons of potable water. This will provide 292 to 2600 ppm peroxyacetic acid and 1240 to 11200 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™ Liquid Sanitizer and Disinfectant solution by wiping, mopping, or as a coarse spray. Allow to soak for at least 10 minutes, then air dry.

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

1. Remove all animals / poultry from the facilities / items / areas to be disinfected.
2. Remove gross particulate, litter, droppings etc. with a warm water flush or by sweeping.
3. Empty all troughs, racks, and other feeding and watering equipment.
4. Wash all items thoroughly with detergent or cleaning solution and rinse with potable water.
5. Prepare a disinfecting solution by adding 3.2 ounces of VigorOx™ Liquid Sanitizer and Disinfectant to 5 gallons of potable water. This provides 292 ppm of peroxyacetic acid and 1240 ppm of hydrogen peroxide.
6. Before starting the treatment ensure that the work area is well ventilated.
7. Saturate surfaces with the diluted product for a period of at least 10 minutes.
8. Thoroughly scrub treated feed equipment i.e., feed racks, troughs, fountains etc. with a detergent and rinse with potable water.

9. Do not return animals / poultry or use equipment until solution has been completely absorbed and air dried.

Poultry Hatchery Disinfection

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

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

VigorOx™ Liquid Sanitizer and Disinfectant is for use in the sanitization of ultra filtration, medical and non-medical institutional/industrial reverse osmosis (RO) membranes and their associated distribution systems.

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™ Liquid Sanitizer and Disinfectant.

1. 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.
3. Remove mineral deposits with an acidic cleaner prior to sanitizing the membranes.
4. Flush the system With RO permeate or similar quality water.
5. Prepare an appropriate volume of 1% solution of the product. This will provide 560 ppm of peroxyacetic acid and 2400 ppm hydrogen peroxide.
6. 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).
7. Recirculate the dilute solution of VigorOx™ Liquid Sanitizer and Disinfectant for a minimum of 10 minutes.
8. Allow membrane elements to soak in the solution for a minimum of 20 minutes.
9. 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 Membranes

1. Isolate incompatible equipment from piping system. This includes activated carbon filters and ion exchange equipment. Turn off power to ultraviolet light units.
2. 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™ Liquid Sanitizer and Disinfectant 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.
3. Recirculate the dilute VigorOx™ Liquid Sanitizer and Disinfectant solution through the system for a minimum of 4 hours. Process usage valves should be opened and closed, to expose internals to the VigorOx™ Liquid Sanitizer and Disinfectant solution.
4. Completely drain the system of dilute VigorOx™ Liquid Sanitizer and Disinfectant 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 than 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™ Liquid Sanitizer and Disinfectant, 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

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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™ Liquid Sanitizer and Disinfectant or the solution and periodically monitor residual peroxygen so that the desired effect is obtained.

2. For continuous addition do not exceed 20 ppm VigorOx™ Liquid Sanitizer and Disinfectant. This will give 1 ppm peroxyacetic acid and 4 ppm hydrogen peroxide. For intermittent feed do not exceed 2000 ppm VigorOx™ Liquid Sanitizer and Disinfectant. This will give 100 ppm peroxyacetic acid and 400 ppm hydrogen peroxide.

Spray Application

Sanitizer and disinfectant solutions, prepared as specified, may be applied as a coarse spray to surfaces to be sanitized or disinfected. Thoroughly wet surfaces, allow to soak for at least 5 minutes (for sanitizing) or 10 minutes (for disinfecting), then air dry.

Fogging

VigorOx™ Liquid Sanitizer and Disinfectant 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 0.30% VigorOx™ Liquid Sanitizer and Disinfectant solution.
4. Allow surfaces to drain thoroughly before operations are resumed.

Note: Before using VigorOx™ Liquid Sanitizer and Disinfectant 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
Label Effective Date: September 2000

ACCEPTED
with COMMENTS
in EPA Letter Dated:

OCT 31 2000

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