

December 14, 2005

Michael T. Novak
Keller and Heckman, LLP
1001 G Street, NW
Suite 500 West
Washington, DC 20001

Subject: Selective Micro Technologies, LLC
Selective Micro Clean Alpha
EPA Registration Number 74986-4
Application Dated: August 29 2005
Receipt Date: August 30, 2005

Dear Mr. Novak:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable with the conditions listed below:

- Addition of disinfectant claims on hard, non-porous surfaces in the presence of 250 ppm hard water and a 5% organic soil load for a contact time of 10 minutes at a 100 ppm ClO₂ dilution for:

Feline calicivirus
Hepatitis A Virus
Human Immunodeficiency Virus type 1
Poliovirus type 1
Rotavirus

Conditions

1. In accordance with DIS/TSS-15 guidelines, add a statement regarding if and how the product should be removed from treated surfaces after the recommended exposure time.
2. On page 2 under the "Special Instructions for Cleaning and Decontaminating Surfaces and Objects . . ." section, change "IG-1" to read "the product or Clean Alpha."

CONCURRENCES

SYMBOL	7576C						
SURNAME	Henson						
DATE	12-14-05						

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General Comments

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

If you have any questions about these comments, please feel free to contact Wanda Henson at (703) 308-6435.

Sincerely,

Emily H. Mitchell
Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510C)



Selective Micro Technologies

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

DANGER: DRY INGREDIENTS. CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE AND CAUSES SKIN BURNS. HARMFUL IF SWALLOWED. WEAR PROTECTIVE EYEWEAR (GOGGLES, FACE SHIELD OR SAFETY GLASSES) WHEN HANDLING DRY INGREDIENTS. WASH THOROUGHLY WITH SOAP AND WATER AFTER HANDLING AND BEFORE EATING, DRINKING OR USING TOBACCO. REMOVE CONTAMINATED CLOTHING AND WASH BEFORE REUSE.

ACTIVATED SOLUTION: HARMFUL IF SWALLOWED. DO NOT GET IN THE EYES OR ON CLOTHING. AVOID CONTACT WITH SKIN. AVOID BREATHING VAPOR FROM CONTAINER SPOUT. WASH THOROUGHLY WITH SOAP AND WATER AFTER HANDLING

PHYSICAL OR CHEMICAL HAZARDS

DRY SODIUM CHLORITE IS INCOMPATIBLE WITH ACIDS, REDUCING AGENTS, COMBUSTIBLE MATERIALS, SULFUR-CONTAINING RUBBER, SOLVENTS AND PAINTS. KEEP ACTIVATED SOLUTION FROM LIGHT AND HEAT. CHLORINE DIOXIDE GAS MAY CONCENTRATE IN OPEN SPACE OF POUCH. ALWAYS OPEN ACTIVATED POUCH, AND DILUTE ACTIVATED SOLUTION, IN WELL-VENTILATED AREA.

NOTE: For use in the institutional or commercial applications discussed below and in the accompanying Technical Bulletin. Not for use in households or where young children may be present. Cap is not child-resistant.

DIRECTIONS FOR USE: IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH THE LABELING.

1. Fill the pouch with tap water (2 liters) to generate the chlorine dioxide solution.
2. WAIT AT LEAST 6 HOURS BEFORE USE TO ENSURE SOLUTION REACHES FULL STRENGTH.
3. Shake gently before use. Direct spout away from face when opening, work in well-ventilated area, and avoid inhaling fumes. Wear protective gloves if hands will come in contact with activated solution during dilution or application.
4. See Technical Bulletin for recommendations regarding dilutions and contact times for specific applications. Before use, verify concentration using *Selective Micro® Chlorine Dioxide Test Strips* to ensure appropriate concentration (see Technical Bulletin for directions if *Test Strips* indicate lower-than-desired concentration).
5. Activate prior to expiration date stamped on pouch. If solution in pouch will not be used up within 72 hours of activation, transfer unused solution to a dark, oxidation-resistant closed or sealed container; store dilutions of solution in a sealed container of the same type (see Tech Bulletin for container details). Store original or diluted solutions in cool place out of direct sunlight (do not store in refrigerator dedicated to food storage). Record activation date and concentration on stick-on label shipped with pouches, and affix to pouch or storage container. Use solution and/or subsequent dilutions within 15 days of activating pouch.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE AND DISPOSAL. STORE IN COOL, DRY, VENTILATED AREA. STORE BELOW 50° C (122° F). KEEP PRODUCT OUT OF DIRECT SUNLIGHT. STORE SEPARATELY FROM WATER AND ACIDS. IF PACKAGE RUPTURES AND CONTENTS SPILL, DO NOT PERMIT CONTACT OF CONTENTS WITH ORGANIC MATERIALS (FOR EXAMPLE: CLOTHING OR COMBUSTIBLE MATERIALS) OR ACIDS. PESTICIDE WASTES ARE TOXIC. IMPROPER DISPOSAL OF EXCESS DRY PESTICIDE IS A VIOLATION OF FEDERAL LAW. IF THIS PRODUCT CANNOT BE USED ACCORDING TO LABEL INSTRUCTIONS, CONTACT YOUR STATE PESTICIDE OR ENVIRONMENTAL CONTROL AGENCY, OR THE HAZARDOUS WASTE REPRESENTATIVE AT THE NEAREST EPA REGIONAL OFFICE FOR GUIDANCE. COMPLETELY EMPTY ACTIVATED SOLUTION IN POUCH INTO APPLICATION EQUIPMENT. THEN DISPOSE OF EMPTY POUCH IN A SANITARY LANDFILL OR BY INCINERATION, OR, IF ALLOWED BY STATE AND LOCAL AUTHORITIES, BY BURNING. IF BURNED, STAY OUT OF SMOKE.

WARRANTY STATEMENT: The Company warrants the product to be free from defects in material and workmanship. THE COMPANY MAKES NO WARRANTY THAT THE GOODS SHALL BE

SELECTIVE MICRO® CLEAN-ALPHA
DISINFECTANT/SANITIZER/TUBERCULOCIDE/VIRUCIDE
FUNGICIDE/ALGAECIDE/SLIMICIDE/DEODORIZER

PRODUCES TWO LITERS OF 500 PPM CHLORINE DIOXIDE SOLUTION WHEN ACTIVATED

When used as directed, this chlorine dioxide-generating product is proven effective as: a **disinfectant** against *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella choleraesuis*, methicillin-resistant *S. aureus*, vancomycin-resistant *Enterococcus faecalis*, *Mycobacterium bovis* (TB) and *Trichophyton mentagrophytes* (athlete's foot); a **fungicide** against *Aspergillus*, *Corona virus*, *Feline Calicivirus*, *Hepatitis A*, *Human Immunodeficiency Virus Type 1 (HIV-1)*, *Poliovirus-1*, and *Rotavirus*; a **sanitizer** against *E. coli* and *E. coli O157:H7*, *S. aureus*, *Salmonella typhimurium* (MDRS), and *Klebsiella pneumoniae*; a **fungicide** against *Penicillium digitatum*, *Botrytis Sp.*, and *Fusarium solani*; and an **algaecide** (*Phormidium boneri*).

KEEP OUT OF REACH OF CHILDREN
DANGER Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 74986-4

Active Ingredient:
Sodium Chlorite 30.5%
Other Ingredients: 69.5%
Total: 100.0%

Amount of Chlorine Dioxide generated = 0.05%

FIRST AID

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on Skin or Clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If Swallowed: Call 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 the poison control center or doctor. Do not give anything by mouth to an unconscious person.

If Inhaled: Remove victim to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for treatment advice. Get medical attention.

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

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

EPA Registration No. 74986-4 EPA Establishment No. 071441-OH-004

Sold by Selective Micro Technologies, LLC
66 Cherry Hill Dr., Suite 230, Beverly, MA 01915

Net Weight of contents 0.44 ounces (12.34 grams)

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MERCHANTABLE. THE COMPANY MAKES NO WARRANTY, EXPRESS OR IMPLIED, EXCEPT SUCH AS IS EXPRESSLY SET FORTH HEREIN. The Company shall not be liable for any incidental or consequential damages for any breach of warranty. The company's liability for any breach of warranty shall be limited to the purchase price of the product.

When used as directed, this product is an effective sanitizer, disinfectant, virucide, tuberculocide, virucide, fungicide, algacide and general-purpose antimicrobial. For all applications, clean surfaces before using product. Apply by mop, sponge, or sprayer, ensuring visible wetness for times specified for these applications, or apply through immersion or clean-in-place application. Wear a NIOSH/MHSA-approved respirator appropriate for chlorine dioxide when using a high-pressurized sprayer.

SANITIZER FOR HARD, NON-POROUS, FOOD-CONTACT SURFACES: Effective food contact surface sanitizer at 5 ppm against *E. coli* and *E. coli* O157:H7, *Salmonella typhimurium* (MDRS), and *Staphylococcus aureus* with an exposure time of 1 minute. Product may be used on previously cleaned food preparation surfaces; fountain drink and beverage dispensers; glassware, plates and eating utensils; food processing equipment, including beer processing equipment and lines, and food conveyor belts. For a 5 ppm solution, use dilution device or sprayer with a 1:100 dilution (one part solution to 99 parts water). See Technical Bulletin for alternative dilution instructions and application specifics.

SANITIZER FOR HARD, NON-POROUS, NON-FOOD-CONTACT SURFACES: Effective non-food contact surface sanitizer at 20 ppm against against *Staphylococcus aureus* and *Klebsiella pneumonia* with an exposure time of 5 minutes. Product may be used on non-food contact surfaces, including floors, walls, and furnishings. For a 20 ppm solution, use dilution device or sprayer with a 1:25 dilution (one part solution to 24 parts water). See Technical Bulletin for alternative dilution instructions and application specifics.

DISINFECTANT OR VIRUCIDE FOR HARD, NON-POROUS SURFACES: Product may be used at 100 ppm with an exposure time of 10 minutes to disinfect hard surfaces in medical or veterinary clinics that may be contaminated with *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, methicillin-resistant *S. aureus*, vancomycin-resistant *Enterococcus faecalis*, *Mycobacterium bovis* (TB) and *Trichophyton mentagrophytes* (athlete's foot), *Corona virus*, *Feline Calicivirus*, *Hepatitis A*, *Human Immunodeficiency Virus Type 1 (HIV-1)*, *Poliovirus-1*, and *Rotavirus*. This product may be used as a disinfectant or virucide on general environmental surfaces. This product may be used to disinfect general environmental surfaces. For a 100 ppm, use a dilution device or sprayer with a 1:5 dilution (one part solution to four parts water). See Technical Bulletin for alternative dilution instructions and application specifics.

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATING SURFACES AND OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS POTENTIALLY CONTAINING HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

- Wear protective barriers such as disposable latex gloves, gowns, masks, and eye coverings when handling items soiled with blood or body fluids.
- Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of 1G-1.
- Blood, other body fluids, and contaminated cleaning materials should be autoclaved and disposed of according to local regulations for infectious waste disposal.

DISINFECTANT FOR CLEAN-IN-PLACE APPLICATIONS FOR POTABLE WATER SYSTEMS: Product may be used to disinfect lines (contaminated with *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, methicillin-resistant *S. aureus*, and vancomycin-resistant *Enterococcus faecalis*) used in fountain drink or other beverage preparation, storage, transfer and dispensing. For a 100 ppm solution (10-minute exposure time), use a dilution device with a 1:5 dilution (one part solution to four parts water); for a 50 ppm solution (20-minute exposure time), use a dilution device with a 1:5 dilution (one part solution to nine parts water). See Technical Bulletin for alternative dilution instructions and application specifics.

ANTIMICROBIAL AND GENERAL CLEANING APPLICATIONS FOR POTABLE WATER SYSTEMS: This product will reduce microbial populations in the potable water holding tanks and lines of recreational vehicles (RV) and boats, in marine and RV wastewater tanks and lines; and fountain drink or other beverage preparation, storage, transfer and dispensing lines and equipment. In addition, it will clean, eliminate odors, and remove organic matter. These uses must be followed by a potable water rinse. For 50 ppm, use one activated pouch (2 liters) for every 50 gallons of capacity, rounding to the next higher number of pouches (for example, use two pouches to treat a 100-gallon tank; for two 80-gallon tanks—total capacity of 160 gallons—use four pouches). See Technical Bulletin for preparation directions and other dilution and application specifics.

ANTIMICROBIAL APPLICATIONS FOR NON-POTABLE WATER SYSTEMS IN HORTICULTURAL SETTINGS: This product may be used to reduce microbial populations in non-potable water used with cut flowers to minimize microbial transfer from water to flower, thereby maintaining freshness and extending shelf-life of cut flowers. For a 5 ppm solution, use a dilution device or sprayer with a 1:100 dilution (one part solution to 99 parts water). See Technical Bulletin for detailed directions and dilution and application specifics.

GENERAL DISINFECTANT, SANITIZER, ALGAECIDE AND FUNGICIDE FOR HORTICULTURAL AND GREENHOUSE APPLICATIONS: For horticultural applications, this product may be used to disinfect (100 ppm/10 minutes or 50 ppm/20 minutes) and sanitize (20 ppm/5 minutes) hard, non-porous surfaces; to treat,

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control, and prevent fungi (5 ppm/1 hour) (*Penicillium digitatum*, *Botrytis Sp.*, *Fusarium solani* & *oxysporum f. sp. Basilicum (Fob)*, and *Trichothium irregulare* & *aphanidermatum*), bacteria (*Erwinia chrysanthemi*), algae (*Phormidium boneri*), and attendant slimes, rusts, leaf spot and mildews; and to remove slimes (50 ppm/12 hours-overnight) & inhibit reemergence (0.25 ppm/continuous treatment) in irrigation and other non-potable water systems. For 100 ppm, use a dilution device or sprayer with a 1:5 dilution (one part solution to four parts water); for 50 ppm, use a 1:10 dilution (one part solution to nine parts water); for 20 ppm, use a 1:25 dilution (one part solution to 24 parts water); for 5 ppm, use a 1:100 dilution (one part solution to 99 parts water); for 0.25 ppm, use a 1:2,000 dilution (one part solution to 1,999 parts water). Concentrations and contact times are application-specific; see Technical Bulletin for detailed directions and other dilution and application specifics.

FRUIT AND VEGETABLE WASH TO EXTEND FRESHNESS AND SHELF-LIFE. This product may be used at 5 ppm for 1 minute to reduce spoilage microorganisms on raw agricultural commodities (RACs) in food processing facilities. To achieve a 5 ppm concentration, begin with a 500 ppm solution and use a dilution device or sprayer with a 1:100 dilution (one part 500 ppm solution to 99 parts water). Spray or dip RACs, and follow with a potable water rinse or by canning, blanching, or cooking. See Technical Bulletin for detailed directions and other dilution and application specifics.