

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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 IG-1  
EPA Registration Number 74986-5  
Application Dated: August 24, 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 ClO<sub>2</sub> 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. Under the "Physical/Chemical Hazards section correct the typographical error "matierials" to "materials."

CONCURRENCES

SYMBOL	7516C						
SURNAME	Henson						
DATE	12-14 05						

**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

## SELECTIVE MICRO® CLEAN 1G-1

DISINFECTANT/SANITIZER/TUBERCULOCIDE/VIRUCIDE

FUNGICIDE/ALGAECIDE/SLIMICIDE/DEODORIZER

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 **virucide** against 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

(See back panel for other cautions)

Active Ingredient:

Sodium Chlorite .....

Other Ingredients: .....

Total: .....

Amount of Chlorine Dioxide generated = 0.05% in 2 liters of water

ACCEPTED WITH COMMENTS  
EPA Letter Dated: DEC 14 2005  
Fungicide, Insecticide, and Rodenticide Act amended for the pesticide, registered under EPA Reg. No. 74986-5

### 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. 74986-5

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)

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS

**DANGER:** DRY INGREDIENT IRRITANT. CAUSES IRRITATION OF EYES AND 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 VAPORS. 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 CONTAINER IN WHICH 1G-1 ENVELOPE IS ACTIVATED. ALWAYS DILUTE ACTIVATED PRODUCT IN WELL-VENTILATED AREA. DO NOT REMOVE 1G-1 FROM CONTAINER OF WATER PRIOR TO COMPLETE GENERATION—6 HOURS AFTER EXPOSURE TO WATER.

**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.

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

1. Open the package, ensuring the 1G-1 envelope inside is not cut. Discard desiccant.
2. To achieve an aqueous solution of 500 ppm chlorine dioxide, immerse (submerge) the 1G-1 envelope in container with 2 liters of water. Close/seal container tightly. Container interior should be dark and resistant to oxidation. See Technical Bulletin for recommendations regarding amount of water, contact times and dilutions for specific applications, and recommended container specifications.
3. WAIT AT LEAST 6 HOURS BEFORE USE TO ENSURE SOLUTION REACHES FULL STRENGTH. DO NOT REMOVE 1G-1 FROM CONTAINER OF WATER PRIOR TO 6 HOURS.
4. Remove 1G-1 from container and mix gently before use. Work in well-ventilated area and avoid inhaling fumes. Wear protective gloves if hands will come into contact with activated solution during dilution or application. Remove envelope from container within 72 hours after activation. Do not reuse the 1G-1. Discard envelope according to instructions below. Before use, verify concentration with *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 package. Store unused solution (and/or subsequent dilutions) in a dark, oxidation-resistant closed or sealed container. Record activation date and concentration on stick-on label shipped with 1G-1s, and affix to storage container. Store activated solution in cool place out of direct sunlight (do not store in refrigerator dedicated to food storage). Use solution and/or subsequent dilutions within 15 days of activation.

#### 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

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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 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, 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. Beginning with a 500 ppm solution, use a dilution device or sprayer with a 1:100 dilution (one part 500 ppm solution to 99 parts water) to achieve a 5 ppm solution. 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 *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. Beginning with a 500 ppm solution, use a dilution device or sprayer with a 1:25 dilution (one part 500 ppm solution to 24 parts water) to achieve a 20 ppm solution. 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), *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. Beginning with a 500 ppm solution: use a dilution device or sprayer with a 1:5 dilution (one part 500 ppm solution to four parts water) to achieve a 100 ppm solution. See Technical Bulletin for detailed directions and other dilution 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. Beginning with a 500 ppm solution: use a dilution device with a 1:5 dilution (one part 500 ppm solution to four parts water) to achieve a 100 ppm solution (10-minute exposure time); or, use a dilution device or sprayer with a 1:10 dilution (one part 500 ppm solution to nine parts water) to achieve a 50 ppm solution (20-minute exposure time). See Technical Bulletin for preparation directions and other dilution 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 1G-1 for every 50 gallons of capacity, rounding to the next higher number of 1G-1s (for example, use two 1G-1s to treat a 100-gallon tank; for two 80-gallon tanks—total capacity of 160 gallons—use four). See Technical Bulletin for detailed 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. Beginning with a 500 ppm solution: use a dilution device or sprayer with a 1:100 dilution (one part 500 ppm solution to 99 parts water) to achieve a 5 ppm solution. See Technical Bulletin for detailed directions and other 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

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... and sanitize (20 ppm/5 minutes) hard, non-porous surfaces; to treat, control, and prevent funguses (5 ppm/1hour) (*Penicillium digitatum*, *Botrytis Sp*, *Fusarium solani* & *oxysporum f. sp. Basillicum* (*Fo* and *Pythium 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. Beginning with a 500 ppm solution: 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 in food processing facilities. Beginning with a 500 ppm solution, use a dilution device or sprayer with a 1:100 dilution (one part 500 ppm solution to 99 parts water) to achieve a 5 ppm solution. 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.