

74986-1

05/05/2004

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

1/4

May 5, 2004

George Misko
Keller and Heckman, LLP
1001 G Street, NW
Suite 500 West
Washington, DC 20001

Subject: Selective Micro Technologies, LLC
Selective Micro Clean-A
EPA Registration No. 74986-1
Application Date: March 2, 2004
Receipt Date: March 3, 2004

Dear Mr. Misko:

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:

- Revised label

Conditions

1. Revise the If Swallowed section of the First Aid statement to comply with the language in PR Notice 2001-1.

"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."

2. Revise the Horticultural/Cut Flowers use pattern to read:

"For 5ppm, use a dilution device or sprayer with a 100:1 dilution"

CONCURRENCES

SYMBOL	7510C	7511C						
SURNAME	Mitchell	Stratton						
DATE	May 5, 2004	5-5-04						

General Comments

This product has made changes to the label which are not reflected on the referenced Technical Bulletin. Selective Micro Technologies, LLC will have to submit a revised Technical Bulletin with all changes incorporated to the Agency. The Technical Bulletin will be reviewed and stamped if acceptable.

A stamped copy of the labeling accepted with conditions is enclosed. Submit a copy of your final printed labeling before distributing or selling the product bearing the revised labeling.

Should you have any questions or comments concerning this letter, please call Wanda Mitchell at (703) 308-6345.

Sincerely,

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



Selective Micro Technologies

SELECTIVE MICRO[®] CLEAN-A DISINFECTANT/SANITIZER/DEODORIZER

PRODUCES TWO LITERS OF 500 PPM CHLORINE DIOXIDE SOLUTION WHEN ACTIVATED

When used as directed, this chlorine dioxide-generating product is proven effective against the following bacteria: *Pseudomonas aeruginosa*; *Staphylococcus aureus*; *Salmonella choleraesuis*; *E coli*; methicillin-resistant *S. aureus*; vancomycin-resistant *Enterococcus*; and *Klebsiella pneumonia*.

KEEP OUT OF REACH OF CHILDREN

DANGER

(See back panel for other cautions)

Active Ingredient:	
Sodium Chlorite:	13.45%
Inert Ingredients:	86.55%
Total:	100.00%

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 a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. 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.

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. 74986-1

EPA Establishment No. 71441-OH-1

Selective Micro Technologies, LLC

66 Cherry Hill Dr., Suite 230, Beverly, MA 01915

Net Weight of contents..... 1.0 ounce (29.2 grams)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: DRY INGREDIENTS: CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. 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: IS 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 IN WELL VENTILATED AREA BEFORE PROCEEDING WITH DILUTION.

NOTE: For use in the institutional or commercial applications discussed below and in the accompanying Technical Bulletin. Not for use in household 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 to generate the chlorine dioxide solution.
2. WAIT AT LEAST 15 HOURS BEFORE USE TO ENSURE SOLUTION REACHES FULL STRENGTH.
3. Shake gently before use. Direct spout away from face when opening.
4. See Technical Bulletin (attached to pouch) for recommendations regarding contact times and dilutions for specific applications.
5. Activate prior to expiration date stamped on pouch. Use solution within 15 days of activating pouch. Store remaining activated solution (if any) in pouch in refrigerator or cool place out of direct sunlight.

When used as directed, this product is an effective sanitizer, disinfectant, and general-purpose antimicrobial. Use in conjunction with *Selective Micro[™] Chlorine Dioxide Test Strips* to ensure appropriate concentration or dilution.

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 MERCHANTABLE OR FIT FOR ANY PARTICULAR PURPOSE. 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.

ACCEPTED
WITH COMMENTS
EPA Letter Dated:

MAY - 5 2004

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No. 74986-1

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When used as directed, this product is an effective sanitizer, disinfectant, and general-purpose antimicrobial.

Food-Contact Non-Porous, Hard Surface Sanitizer. Effective food contact surface sanitizer at 5 ppm against *E. coli* 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 5 ppm concentration, use dilution device or sprayer with a 100:1 dilution. See Technical Bulletin for alternative dilution instructions and application specifics.

Non-Food-Contact Non-Porous, Hard Surface Sanitizer. 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. For 20 ppm, use dilution device or sprayer with a 25:1 dilution. See Technical Bulletin for alternative dilution instructions and application specifics.

HARD, NON-POROUS SURFACE DISINFECTANT: Product may be used to disinfect hard surfaces in medical or veterinary clinics that may be contaminated with *Staphylococcus aureus*, *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, methicillin-resistant *S. aureus*, and vancomycin-resistant *Enterococcus*. This product may be used to disinfect general environmental surfaces. For 100 ppm, use a dilution device or sprayer with a 5:1 dilution. See Technical Bulletin for alternative dilution instructions and application specifics.

GENERAL ANTIMICROBIAL APPLICATIONS FOR POTABLE WATER SYSTEMS:

This product may be used to 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. These uses must be followed by a potable water rinse. For 100 ppm, use a dilution device or sprayer with a 5:1 dilution. See Technical Bulletin for alternative dilution instructions and application specifics.

GENERAL ANTIMICROBIAL APPLICATIONS FOR NON-POTABLE WATER

SYSTEMS: 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. For 100 ppm, use a dilution device or sprayer with a 5:1 dilution. See Technical Bulletin for alternative dilution instructions and application specifics.