74986-1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

04/14/2004

1/4

April 14, 2004

George G. Misko
Agent for Selective Micro Technologies
c/o Keller and Heckman LLP
1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001

Subject: Selective Micro Clean-A
EPA Registration No. 74986-1
Application Date: March 16, 2004
Receipt Date: March 16, 2004

Dear Mr. Misko:

This acknowledges receipt of your notification, submitted under the provision of PR Notice 98-10, FIFRA section 3(c)9.

Proposed Notification

- correction of typographical error

General Comments

Based on a review of the material submitted, the following comments apply:

The notification application is acceptable and a copy has been inserted in your file for future reference.

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

Sincerely,

Wanda Mitchell
Product Reviewer.32
Regulatory Management Branch II
Antimicrobials Division (7510C)

CONCURRENCES								
SYMBOL	7510C	7510C						
SURNAME	E Bero	Mitchell						
DATE	4/14/04	4-14-04						

EPA Form 1320-1A (1/90) Printed on Recycled Paper OFFICIAL FILE COPY

Please read Instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA United States Environmental Protection Agency Washington, DC 20460

☐ Registration ☐ Amendment ☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
74986-1	Wanda Mitchell	☑ None ☐ Restricted
4. Company/Product (Name)	PM#	
SELECTIVE MICRO CLEAN-A	32	

5. Name and Address of Applicant *(Include ZIP Code)*
Selective Micro Technologies, LLC
66 Cherry Hill Drive, Suite 230
Beverly, MA 01915

☐ *Check if this is a new address*

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. N/A

Product Name _____

Section II

☐ Amendment - Explain Below
☐ Resubmission in response to Agency Letter dated _____.
☑ Notification - Explain below.
☐ Final printed labels in response to Agency Letter dated _____.
☐ "Me Too" Application.
☐ Other - explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of typographical correction in Directions for Use per PR Notice 98-10.
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penaltires under section 12 and 14 of FIFRA.

Section III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
☐ Yes* ☑ No	☑ Yes ☐ No		☐ Yes ☑ No		☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☑ Other (Specify) metallized polypropylene
* *Certification must be submitted.*	If "yes," Unit Package wgt.	No. per container	If "Yes," Package wgt.	No. per container	
	1.0 oz/29.2 g	25 average			

3. Location of Net Contents Information	4. Size(s) of Retail Container	5. Location of Label Directions
☑ Label ☐ Container	2 liters	☑ On Label ☐ On Labeling accompanying product

6. Manner in Which Label is Affixed to Product ☐ Lithograph ☑ Paper glued ☐ Stenciled ☐ Other (_____)

Section IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
George G. Misko	Authorized Agent and Attorney	(202) 434-4170

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false for misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Howard Parris	Partner
4. Typed Name	5. Date
Howard L. Parris, Jr.	March 16, 2004

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 cautionary statements)

NOTIFICATION
Date Reviewed: 7/16/04
Reviewed By: E. Berg

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 unavailable, 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-R EPA Establishment No. 71441-OH-4

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 ACIVATED 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 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 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.

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When used as directed, this product is an effective [illegible]tizer, disinfectant, and general-purpose antimicrobial.

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