74986-4

12/14/2011 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

DEC 14 2011

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Jeffrey B. Thomas Selective Micro Technologies 4449 Easton Way (2nd Floor) Columbus, OH 43219

Subject: Selectrocide 2L500 EPA Reg. No. 74986-4 Application Dated: November 28, 2011 Receipt Dated: December 7, 2011

Dear Mr. Thomas:

The following notification submitted in connection with registration under the provisions of PR Notice 98-10, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)9 is acceptable.

Proposed Notification:

• To remove the Mycobacterium bovis (TB) claim,

Comments:

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

The application for notification as referenced above is acceptable. A copy has been placed in our records for future reference.

Should you have any questions concerning this letter, please contact Wanda Henson at <u>Henson.Wanda@epa.gov</u> or call (703) 308-6345.

Sincerely,

Monisha Harris Product Manager (32) Regulatory Management Branch II Antimicrobials Division (7510P)

CONCURRENCES							
SYMBOL	N 7510P			200000000000000000000000000000000000000			
SURNAME					405614046062666464		
DATE	12-14-11						

EPA Form 1320-1A (1/90)

OFFICIAL FILE CO

Please read instructions on reverse before completing form.		Form Approve	JMB No. 2070-00	60 Print Form
United State Environmental Protect Washington, DC	ction Agency	×	Registration Amendment Other	OPP Identifier Number
Applica	tion for Pestici	de - Section	l	
1. Company/Product Number Selective Micro Technologies Selectrocide 2L500		2. EPA Product Manager 3. Proposed Classification		
4. Company/Product (Name) Selectrocide 2L500	PM# Numl	PM# None Restricted		
5. Name and Address of Applicant <i>(Include ZIP Code)</i> 4449 Easton Way 2nd Floor Columbus, Ohio 43219	(b)(i), n to: EPA J	ny product is sir Reg. No ^{EPA 1}	nilar or identical in eg. 74986-4	ith FIFRA Section 3(c)(3) composition and labeling
Check if this is a new address		ct Name	ctrocide 2L500	
	Section -		·····	
Amendment - Explain below. Resubmission in response to Agency letter dated		Final printed lab Agency letter da "Me Too" Applie		
Notification - Explain below.		Other - Explain I	elow.	ς ς ας ας ς ς
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Yes* X Yes No X Yes * Certification must be submitted If "Yes" Unit Packaging wgt. (44 oz) No. per container 3. Location of Net Contents Information 4. Size(s) X Label Container	Water Soluble F Yes No If "Yes" Package wgt Retail Container	Vackaging No. per container	2. Type of Contai C c c c C c c c c	ctions
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EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.



4449 Easton Way 2nd floor Columbus Oh 43219

November 2011

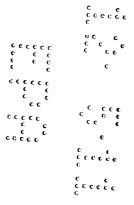
Dear Monisha,

Enclosed please find updated labels for Selective Micro Technologies products EPA number 74986-4. There are two copies of each, one that points out the edits and one that does not. As discussed the TB claims have been removed. Thanks very much.

Sincerely,

Mor B Homa

Jeffrey B. Thomas Selective Micro Technologies



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Selectrocide[®] -2L500-

DISINFECTANT/SANITIZER/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 enterica, methicillin-resistant S. aureus (MRSA). vancomycin-resistant Enterococcus faecalis. Trichophyton mentagrophytes (athlete's foot), Listeria monocytogenes, and Candida albicans; a sanitizer against E. coli (and E. coli O157.H7), S. aureus, Salmonella typhimurium (MDRS), Klebsiella pneumonia, and Listeria monocytogenes; a fungicide against Penicillium digitatum, Botrytis Sp. and Fusarium solani; and an algaecide (Phormidium boneri), *Viruses: Corona virus, Feline Calicivirus, Hepatitis A virus, Human Immunodeficiency virus type 1 (HIV-1), Poliovirus-1, Rotavirus, Influenza-A virus, Rhinovirus type 37, Canine Parvovirus, Adenovirus type 5, Herpes Simplex virus type 2, Vaccinia virus, and Norovirus (feline calici used as testing surrogate); *kills Pandemic 2009 H1N1 Influenza A virus (formerly called swine flu).

See Technical Bulletin (page 3) for ATCC designation numbers of the abovelisted organisms.

KEEP OUT OF REACH OF CHILDREN DANGER

(See back panel for other cautions)

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Active ingredient.	
Sodium Chlorite:	
Other Ingredients:	
Total:	

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				
Manufactured for:Selective Micro Technologies	4449 Easton Way - 2 nd FL Colu	mbus, OH 43219			
www.selectivemicro.com					
Net Weight of contents					

NOTIFICATION Deter Teviewed: Burgenerad BV:



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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

<u>DANGER:</u> 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: CAUSES MODERATE EYE IRRITATION. AVOID CONTACT WITH EYES, SKIN, OR CLOTHING. AVOID BREATHING VAPORS. WASH THOROUGHLY WITH SOAP AND WATER AFTER HANDLING AND BEFORE EATING, DRINKING, CHEWING GUM OR USING TOBACCO.

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.

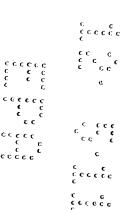
NOTE: For use in the institutional or commercial applications discussed below and in the accompanying Technical Bulletin. Not for use in households or where young children may be present. Cap is not child-resistant.

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. NONREFILLABLE CONTAINER. DO NOT REUSE OR REFILL THIS CONTAINER. COMPLETELY EMPTY ACTIVATED SOLUTION IN POUCH INTO APPLICATION EQUIPMENT. OFFER FOR RECYCLING, IF AVAILABLE, OR 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, EXPRESSED 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, on hard, non-porous surfaces (e.g., stainless steel, brass, glass, vinyl, PVC, polypropylene), this product is an effective sanitizer, disinfectant, virucide*, fungicide, algaecide, general-purpose antimicrobial and cleaner for use in a wide range of applications, including but not limited to: hospitals; medical & veterinary facilities; pharmaceutical production facilities, including equipment (e.g., ultracentrifuges); wineries, breweries, and beverage / bottling plants; laboratories and other clinical settings; potable and non-potable water systems and attendant equipment & tubing; restaurants and food processing plants; and greenhouses/horticultural settings. Heavily soiled surfaces must be pre-cleaned prior to treatment. 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 and under other circumstances detailed in the Technical Bulletin.



DIRECTIONS FOR USE: IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH THE LABELING. READ THE ENTIRE LABEL AND USE STRICTLY IN ACCORDANCE WITH PRECAUTIONARY STATEMENTS AND USE.

FOR POUCH SIZE OF .44 OUNCES (12.34 GRAMS) USE:

- 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 TO REACH 500PPM.
- 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 48 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.

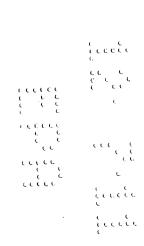
FOR POUCHE SIZE OF .44 OUNCES (12.34 GRAMS) USE THE FOLLOWING GENERAL DILUTIONS AND TABLE

General Dilution Instructions: All dilutions begin with a stock solution at a nominal concentration of 500 ppm, except when the product is activated directly to the application concentration (see technical bulletin). Except where otherwise directed, or for other use concentrations (see technical bulletin), use the following dilution instructions to achieve the use concentration indicated:

To Achieve Use	Use Dilution Device or Sprayer With a Dilution Ratio of:					
Concentration of:						
100 ppm	1:5 (one	part 500 ppm solution to 4 parts water)				
50 ppm	1:10 (one	part 500 ppm solution to 9 parts water				
20 ppm	1:25 (one	part 500 ppm solution to 24 parts water)				
5 ppm	1:100 (one	part 500 ppm solution to 99 parts water)				
0.25 ppm	1:2,000 (one	part 500 ppm solution to 1,999 parts water)				

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. Dilute to 5 ppm as table above specifies. 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*, *Klebsiella pneumonia* and *Listeria monocytogenes* with an exposure time of 5 minutes. Product may be used on non-food contact surfaces, including floors, walls, furnishings, and equipment. Dilute to 20 ppm as table above specifies. See Technical Bulletin for alternative dilution instructions and application specifics.



8

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 enterica, Pseudomonas aeruginosa,* methicillin-resistant *S. aureus (MRSA),* vancomycin-resistant *Enterococcus faecalis, Trichophyton mentagrophytes* (athlete's foot), *Listeria monocytogenes,* and *Candida albicans; and the following *viruses:* Corona virus, Feline Calicivirus, Hepatitis A virus, Human Immunodeficiency virus type 1 (HIV-1), Poliovirus-1, Rotavirus, Influenza-A virus, Rhinovirus type 37, Canine Parvovirus, Adenovirus type 5, Herpes Simplex virus type 2, Vaccinia virus, Norovirus and pandemic 2009 H1N1 Influenza A virus. This product may be used as a disinfectant or virucide on general environmental surfaces. Dilute to 100 ppm as table above specifies. 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) (at 100 ppm/10 min. contact time)

- 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 2L500 solution.
- Blood, other body fluids, and contaminated cleaning materials should be autoclaved and disposed of according to local regulations for infectious waste disposal.

<u>DISINFECTANT FOR CLEAN-IN-PLACE APPLICATIONS FOR POTABLE WATER SYSTEMS:</u> Product may be used to disinfect lines (contaminated with *Staphylococcus aureus, Salmonella enterica, Pseudomonas aeruginosa,* methicillin-resistant *S. aureus,* vancomycin-resistant *Enterococcus faecalis,* and *Candida albicans)* used in fountain drink or other beverage preparation, storage, transfer and dispensing. Dilute as table above specifies to either 100 ppm solution for a 10-minute exposure time or to 50 ppm solution for a 20-minute exposure time. 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. Because the application is designed for overnight uses, does not require filled tanks, and involves volumes of solution dependent on tank capacity and level of contamination, users should consult page 8 of the Technical Bulletin for application details. (For example, in a potable water tank system with two 80-gallon tanks [a capacity of 160 gallons in total] and a level of contamination judged to be high, then four pouches will be required, determined and applied as described in the Technical Bulletin.)

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. Dilute to 5 ppm as table above specifies. 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, control, and prevent fungi (5 ppm/1 hour) (Penicillium digitatum, Botrytis Sp, Fusarium solani & oxysporum f. sp. Basilicum (Fob), 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. Concentrations and contact times are application-specific; dilute to use concentrations



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as table above specifies. See Technical Bulletin for detailed directions and other dilution and application specifics.

<u>FRUIT AND VEGETABLE WASH TO EXTEND FRESHNESS AND SHELF-LIFE.</u> This product may be used at 5 ppm for 1 minute to reduce spoilage microorganisms on raw agricultural commodities (RACs) in food processing facilities. Spray or dip RACs, and follow with a potable water rinse or by canning, blanching, or cooking. Dilute to 5 ppm as table above specifies. See Technical Bulletin for detailed directions and other dilution and application specifics.

ANTIMICROBIAL APPLICATIONS TO CONTROL THE BUILDUP OF MICROBES IN PROCESS WATERS FOR FRUIT AND VEGETABLE RINSE AND ASSOCIATED TANKS, FLUMES, AND LINES. This product will inhibit the build-up of microbes in water used in the processing of fruits and vegetables. Target residual concentrations of chlorine dioxide between 0.25 ppm and 5.0 ppm are recommended to control microbial buildup. Dilute to 0.25 ppm or 5 ppm as table above specifies, or follow directions in Technical Bulletin. Inject chlorine dioxide continuously or intermittently to the system to maintain desired concentration. The frequency and volume of replenishment will vary with the degree of contamination in the fruits and vegetables being processed, target concentration, and process design. See Technical Bulletin for preparation directions and other dilution and application specifics.

ANTIMICROBIAL TREATMENT FOR POULTRY DRINKING WATER. This product may be used at up to 5 ppm but not less than an application concentration sufficient to ensure a residual concentration of 0.25 ppm to control microorganisms in drinking water intended for poultry. Dilute to 5 ppm as specified above, or use directly in system with automatic, on-demand injection system metered to produce desired end concentration up to 5 ppm. Application particulars will depend upon metering system, frequency of replenishment, and capacity of drinking container. See Technical Bulletin for activation instructions and other dilution and application specifics.

SANITIZING FINAL RINSE OF PRE-CLEANED OR NEW RETURNABLE OR NON-RETURNABLE CONTAINERS. This product may be used as a final sanitizing rinse for plastic, glass or metal returnable and non-returnable bottles, cans, caps, kegs, and beverage containers. Beginning with a 500 ppm solution, use a device with a 6:100 dilution ratio (six parts solution to 94 parts water) to produce an end application concentration of 30 ppm. Alternatively, activate directly to the end concentration of 30 ppm using directions in the Technical Bulletin. Rinse bottles, cans, or other containers with the use solution, ensuring visible wetness. Allow to drain dry. See Technical Bulletin for preparation directions and other dilution and application specifics.

ANTIMICROBIAL AND GENERAL CLEANING USES FOR NON-POTABLE WATER APPLICATIONS INVOLVING RECIRCULATING WATER SYSTEMS (E.G., COOLING TOWERS, PAPER MILLS, AND DECORATIVE OR ORNAMENTAL FOUNTAINS): This product will help remove, control and inhibit reemergence of slimes, algae, fungi, and other organic buildups in recirculating water systems. For initial or remedial treatment in cases of visually-obvious build-up of slime, algae, or organic matter: beginning with a 500 ppm solution, for each 1,000 gallons or cooling or fountain water, add 10 gallons of the 500 ppm solution to achieve a residual concentration of chlorine dioxide of approximately 5 ppm. Circulate water in normal system operation. Repeat daily until desired results are achieved. For continuous or periodic treatment: beginning with a 500 ppm solution, for each 1,000 gallons of cooling or fountain water, add one gallon of the 500 ppm solution to achieve a residual concentration of chlorine dioxide of approximately 5 ppm. Circulate water in normal system operation. Repeat daily until desired results are achieved. For continuous or periodic treatment: beginning with a 500 ppm solution, for each 1,000 gallons of cooling or fountain water, add one gallon of the 500 ppm solution to achieve a residual concentration of chlorine dioxide of approximately 0.5 ppm. Circulate water in normal system operation. See Technical Bulletin for activation instructions and other dilution and application specifics.

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