12/30/2013



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Mr. Jeff B. Thomas, President and CEO Selective Micro Technologies, LLC 4449 Easton Way, Second Floor Columbus, OH 93219

DEC 30 2013

Subject: 98-10 Revising Product Labels per April 8, 2013 Agency Letter Selectrocide 2L500 EPA Registration Number: 74986-4 Application Date: October 31, 2013 EPA Receipt Date: November 7, 2013

Dear Mr. Thomas:

This acknowledges receipt of your Notification application, submitted under the provisions of FIFRA 3(c)9 and PR Notice 98-10.

## Notification Purpose:

"..we are notifying EPA that the labels for Alternate Brand Name (ABN) Selectrocide® 2L500 Abridged and the Master Label for Selectrocide 2L500, both of which are currently accepted labels on file with the EPA,...are being updated to include accepted label amendment language per EPA Letter dated April 8, 2013. Enclosed is the required paper to support this ABN."

Specifically, Selective Micro Technologies, LLC is eliminating the Claim against *Clostridium difficile – spore form* on these Product Labels.

Selective Micro Technologies, LLC is submitting the following new Alternate Brand Name for **EPA Reg. No. 74986-4**:

## Selectrocide® 2L500 Abridged.

## General Comments:

Based on the review of the information submitted, the following comments apply. The Notification is **Acceptable.** A copy of the **accepted** Notification is attached in **Regulatory File Jacket 74986-4** for future reference.

If you have questions or comments with regard to this Agency Letter, please contact me by email at **Fuller.Demson@epa.gov** by telephone at **703-308-8062.** When you are submitting information or data in response to this Agency Letter, please send a copy of this Agency Letter with your response in order to facilitate processing.

Sincerely yours,

Demson Fuller, EPA Product Manager 32 Regulatory Management Branch II Antimicrobials Division 7510P

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EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.



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## Via Certified Mail

Document Processing Desk (DCI/PRD) Office of Pesticide Programs US Environmental Protection Agency Room S-4900, One Potomac Yard 2777 S. Crystal Drive Arlington, Virginia 22202

- To: Monisha Harris Team Leader 32 Regulatory Management Branch
- Re: Registrant: Selective Micro Technologies, LLC ("SMT") Product: Selectrocide® 2L500 (EPA Reg. 74986-4) Notification – Addition of EPA Accepted language to an Alternate Brand Name per PR Notice 98-10

Dear Ms. Harris:

On behalf of Selective Micro Technologies, LLC ("SMT"), we are notifying EPA that the labels for Alternate Brand Name (ABN) Selectrocide® 2L500 Abridged and the Master Label for Selectrocide 2L500, both of which are currently accepted labels on file with the EPA, and marketed under Product: Selectrocide® 2L500 (EPA Reg. 74986-4), are being updated to include accepted label amendment language per EPA letter dated April 8th, 2013. Enclosed is the required paperwork to support this ANB.

This notification is consistent with provisions of PR Notice 98-10 and EPA regulations at 40 C.F.R. § 152.46, and no other changes have been made to the confidential statement of formula of this product nor have any changes been made to the Selectrocide 2L500 Technical Bulletin, which is the master label technical bulletin for all ABN's identified under Product Reg. No. 74986-4. I understand that it is a violation if 18 U.S.C. § 1001 to willingly make any false statement to the EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 C.F.R. § 152.46, this product may be in violation of FIFRA, and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

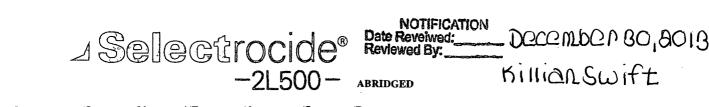
Please contact me should you have any questions regarding this notification.

Sincerely,

Mr. Jeff Thomas, Selective Micro Technologies, LLC President and CEO

Joffor B Thomas

4449 Easton Way – 2<sup>nd</sup> FL Columbus, OH 43219 selectivemicro.com 855-256-8299



# $\textbf{D} is infect ant/Sanitizer/Virucide*/Fungicide/Algaecide/Slimicide/Deodorizer}$

[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* 0157:H7), S. *aureus, Salmonella enterica, methicillin-resistant 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, <i>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 symine flu). See Technical Bulletin (page 3) for ATCC designation numbers of the above-listed organisms.

## 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%

Net Weight of contents......0.44 ounces (12.34 grams)

### **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,

doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu).

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

EPA Registration No. 74986-4

Active Ingredient

Manufactured for:Selective Micro Technologies 4449 Easton Way - 2<sup>nd</sup> FL Columbus, OH 43219 www.selectivemicro.com

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

EPA Establishment No. 071441-OH-004

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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, CHEWING GUM, USING TOBACCO OR USING THE TOILET. 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, generalpurpose 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 nonpotable 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.

- 1.) Fill the pouch with tap water (2 liters) to generate the chlorine dioxide solution.
- 2.) Wait at least 2 hours before use to ensure solution reaches full strength to reach 500ppm.
- 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 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.

## 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	

Concentration of:	L	
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, for Hard, Non-Porous, Non-Food-Contact Surfaces. Disinfectant or Virucide\* For Hard, Non-Porous Surfaces, Disinfectant for Clean-in-Place Applications for Potable Water Systems, Antimicrobial and General Cleaning Applications for Potable Water Systems, Antimicrobial Applications for Non-Potable Water Systems in Horticultural settings, General disinfectant, sanitizer, algaecide and fungicide for horticultural and greenhouse applications, Fruit and Vegetable Wash to Extend Freshness and Shelf-Life, Antimicrobial Applications to control the buildup of microbes in process waters for Fruit and vegetable rinse and associated tanks, flumes, and lines, Antimicrobial Treatment for Poultry Drinking Water, Sanitizing final rinse of pre-cleaned or new returnable or non-returnable containers, 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).

Pease reference Master Label Technical Bulletin for Detailed Use Patterns and Dilution Rates.

# ⊿Selectrocide® -21500-ABRIDGED

DISINFECTANT/SANITIZER/VIRUCIDE\*/FUNGICIDE/ALGAECIDE/SLIMICIDE/DEODORIZER IPRODUCES 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 above-listed organisms.

## **KEEP OUT OF REACH OF CHILDREN** DANGER

(See back panel for other cautions)

Active ingredient.	
Sodium Chlorite:	
Other Ingredients:	
Total:	
Amount of Old Store Div	

Amount of Chlorine Dioxide generated = 0.05%

Active Ingradients

Net Weight of contents......0.44 ounces (12.34 grams)

EPA Establishment No. 071441-OH-004

## **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,

doctor, or going for treatment. For emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm Pacific Time (NPIC Web site: www.npic.orst.edu).

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

EPA Registration No. 74986-4

Manufactured for:Selective Micro Technologies 4449 Easton Way - 2<sup>nd</sup> FL Columbus, OH 43219 www.selectivemicro.com

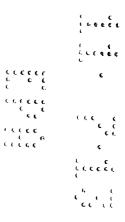
## **PRECAUTIONARY STATEMENTS**

## HAZARDS TO HUMANS AND DOMESTIC ANIMALS

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, CHEWING GUM, USING TOBACCO OR USING THE TOILET. REMOVE CONTAMINATED CLOTHING AND WASH BEFORE REUSE. ACTIVATED SOLUTION: CAUSES MODERATE EYE IRRITATION. AVOID CONTACT WITH EYES, SKIN, OR CLOTHING. BREATHING VAPORS. WASH THOROUGHLY WITH SOAP AND WATER AFTER HANDLING AND BEFORE EATING, DRINKING, CHEWING GUM OR USING TOBACCO.

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#### **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

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, generalpurpose 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 nonpotable 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.

- 1.) Fill the pouch with tap water (2 liters) to generate the chlorine dioxide solution.
- 2.) Wait at least 2 hours before use to ensure solution reaches full strength to reach 500ppm.
- 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).
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Concentration of:	
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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, for Hard, Non-Porous, Non-Food-Contact Surfaces. Disinfectant or Virucide\* For Hard, Non-Porous Surfaces, Disinfectant for Clean-in-Place Applications for Potable Water Systems, Antimicrobial and General Cleaning Applications for Potable Water Systems, Antimicrobial Applications for Non-Potable Water Systems in Horticultural settings, General disinfectant, sanitizer, algaecide and fungicide for horticultural and greenhouse applications, Fruit and Vegetable Wash to Extend Freshness and Shelf-Life, Antimicrobial Applications to control the buildup of microbes in process waters for Fruit and vegetable rinse and associated tanks, flumes, and lines, Antimicrobial Treatment for Poultry Drinking Water, Sanitizing final rinse of pre-cleaned or new returnable or non-returnable containers, 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).

Pease reference Master Label Technical Bulletin for Detailed Use Patterns and Dilution Rates.