

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

June 9, 2005

Kim Davis, CC, APC, Manager
Agent for ConSeal International, Inc.
c/o RegWest Company, LLC
30856 Rocky Road
Greeley, CO 80631-9375

Subject: SaniCide-2
EPA Registration No. 58300-18
Application Date: May 11, 2005
Receipt Date: May 12, 2005

Dear Ms. Davis:

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

Proposed Notification

- Addition of NSF logo and text

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 Y. Henson
Product Reviewer (32)
Regulatory Management Branch II
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL	7510C	7510C						
SURNAME	E. D. Reg	HENSON						
DATE	6-9-05	6-9-05						

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Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060.

United States Environmental Protection Agency 1200 Pennsylvania Avenue, N.W. Washington, DC 20460-0001	<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number <h2 style="text-align: center;">Notification</h2>
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Application for Pesticide – Section I

1. Company/Product Number EPA Reg. No. 58300-18	2. EPA Product Manager Emily Mitchell	3. Proposed Classification
4. Company/ Product (Name) SaniCide-2	PM # 32	<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
5. Name and Address of Applicant (Include ZIP Code) ConsSeal International, Inc. c/o RegWest Company, LLC 30856 Rocky Road Greeley, CO 80631-9375 <input type="checkbox"/> 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. _____ Product Name _____

Section – II

<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input checked="" type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated 03/01/05 <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below.
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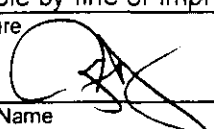
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)
Submit final printed label and label revision notification per PR Notice 98-10 (label revision to add NSF information) (Refer to the Reference Label)

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 the 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 penalties under sections 12 and 14 of FIFRA.

Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
*Certification must be submitted	If "Yes" Unit Packaging Wgt.	No. Per Container	If "Yes" Packaging Wgt.	No. Per Container	<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other (Specify): _____
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling Accompanying Product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Stenciled <input type="checkbox"/> Paper glued <input type="checkbox"/> Other _____					

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application).		
Name Kim Davis, CC, APC, Manager	Title Consultant/Agent	Telephone No. (Include Area Code) (970) 353-0611 kim@regwest.com
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 or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received, (Stamped)
Signature  3. Title Consultant/Agent		
4. Typed Name Kim Davis, CC, APC, Manager		
5. Date May 11, 2005		

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AB 8482 5867 2312

May 11, 2005



Ms. Emily Mitchell, Product Manager 32
Document Processing Desk – **NOTIF/FPL**
Office of Pesticide Programs - **7504C**
U.S. Environmental Protection Agency
1801 South Bell Street
Crystal Mall #2, Room 308
Arlington, VA 22202-4501

Dear Ms. Mitchell:

Subject: ConSeal International, Inc.
SaniCide™-2
EPA Reg. No. 58300-19

On behalf of its client **ConSeal International, Inc.**, RegWest Company, LLC is submitting the attached materials as notification of final printed labeling and a label revision notification. RegWest Company will act as sole agent in this endeavor.

Attached are the following:

1. Application for Pesticide: Notification
2. Two final printed labels
3. One **Reference Label** which illustrates the label revision
4. One Draft label which incorporates the label revision

The market label has been reduced to fit on the 8.5 x 11" paper; therefore, it is not very easy to read. I'm including the draft label for use in the PPLS system.

We're making one revision to the label, and that is the addition of the NSF logo and verbiage.

Please contact me at (970) 353-0611 or kim@regwest.com if you require additional information or have any questions.

Regards,
RegWest Company, LLC

Kim Davis, CC, APC, Manager
Consultant/Agent

Attachments

cc: CII – Perry, S.

20856 Rocky Road
Greeley, CO 80631-9375
970-353-0611
970-353-0613 Fax
Kim@regwest.com

PRECAUTIONARY STATEMENTS
Hazards to Humans and Domestic Animals

CAUTION

Causes moderate eye irritation. Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes or clothing. Thoroughly wash with soap and water after handling.

First Aid

Have the product container or label with you when calling a poison control center or doctor or when going for treatment.

If Swallowed: Immediately call a poison control center or doctor for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

If on Skin or Clothing: Take off contaminated clothing. Immediately rinse skin with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

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 Inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

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

Physical or Chemical Hazards

Stabilized chlorine dioxide is a strong oxidizing agent. Contamination with other materials such as acids, chlorine, organic chemicals, etc. may cause a chemical reaction, resulting in evolution of chlorine dioxide gasses and heat. Explosion and/or fire could result. Chlorine dioxide is a poisonous explosive gas. Keep all chemical and foreign materials away from this solution.

Environmental Hazards

This product is toxic to fish and aquatic organisms. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other public waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State water board or Regional Office of the EPA.

Emergency Handling

In case of contamination or decomposition, do not reseal container, isolate in an open, well-ventilated area and flood with large volumes of water. Cool unopened drums in vicinity by water spray.

Notice: Seller expressly warrants that the product conforms to its chemical description. There are no warranties associated with the sale of this product, either express or implied, including but not limited to, the warranties of fitness for a particular purpose or use.

SaniCide™-2

2% Aqueous Stabilized Chlorine Dioxide

**Mushroom and Vegetable
Rinse Applications
Disinfectant/Deodorizer/Slimicide**

**Biological Control in Paper Mills, Food
Processing Flumes, Water Treatment
Equipment, Petroleum Recovery, Hospital
Disinfecting, Cutting Oils, Cooling Towers
and Hard Surface Disinfection/Sanitation of
Food Processing Equipment**

For Institutional or Industrial Use

Active Ingredient:	
Chlorine Dioxide	2%
Other Ingredients	98%
Total	100%

Keep Out of Reach of Children

CAUTION

See side panel for additional precautionary statements.

EPA Reg. No. 58300-19

EPA Est. 58300-MA-1



NSF International certifies that this product conforms to the requirements of ANSI/NSF Standard 60 - Drinking Water Treatment Chemicals - Health Effects with maximum use levels for potable water of 10 ppm.

Net Contents: _____ Gallons

ConSeal International, Inc.
90 Kerry Place, Suite 2
Norwood, MA 02062
(781) 278-0010
www.consealint.com

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling

General Information

Refer to *Product Data* section before using this product in the generation of chlorine dioxide for biological control in Mushroom/Vegetable Processing/Canning operations and Biological Control in Paper Mills, Food Processing Flumes, Water Treatment Equipment, Petroleum Recovery, Hospital Disinfecting, Cutting Oils, Cooling Towers and Hard Surface Disinfection/Sanitation of Food Processing Equipment.

1. Prior to sanitization or disinfectant treatments, thoroughly clean all surfaces/areas to be treated with a suitable detergent followed by a clean potable water rinse. Remove all gross food particles and filth using appropriate methods such as spray, dip, soak, wash, pre-flush, pre-scrape or pre-soak.

2. When preparing activated solutions: Prepare only in well-ventilated area. Avoid breathing fumes produced while activator is dissolving. Allow 15 minutes' reaction time. As an alternate activation method, adjust the pH to 4.0 with acetic, citric, phosphoric, sulfuric or hydrochloric acid; or add 0.25 to 0.5 grams of DRA-2 per gallon of water.

3. When spraying or fogging disinfectant/sanitizing solutions: Solutions may be irritating when inhaled. During spraying or fogging operations wear a NIOSH/MSHA-approved respirator appropriate for chlorine dioxide. Do not reuse activated solutions; apply only freshly-made solutions for disinfection or sanitization.

4. Chemical feed pumps and injectors must be chlorine-resistant for best operation. To extend freshness and shelf life, confirm available chlorine dioxide levels using a SaniCide™ test kit, available from Con-Seal.

**Mushroom and Vegetable Processing
and Canning Operations
Product Data**

In Mushroom Facilities, such as mushroom production, spawn productions, mushroom processing and cannery operations: Use as a terminal sanitizing rinse for stainless steel tanks, transfer lines, on-line equipment, picking baskets, picking utensils and other food contact surfaces.

1. Preparation of sanitizing solution: In a clean plastic container mix 3 1/2 fl. oz. of SaniCide™-2 with 5 gallons of clean potable water and 1.2 grams of DRA-1. This solution will yield a working solution containing 100 ppm available chlorine dioxide.

2. To apply: Flush picking baskets, line equipment or other food contact surfaces with active solution, making sure surface area is thoroughly wet for at least 1 minute. After sanitizing, drain treated baskets or equipment and allow to air dry. Treat after each use or production run. Discard solution after each use.

To Disinfect Walls, Ceilings and Floors:

1. Preparation of active disinfecting solution: Per gallon of working solution mix, in a clean plastic container, 3 1/2 fl. oz. of SaniCide™-2 with 1 gallon of clean potable water and 1.2 grams of DRA-1. This will yield a working solution containing 500 ppm available chlorine dioxide.

2. To apply: Spray disinfectant solution onto surfaces using a suitable spraying device and making sure that the area is thoroughly wet for at least 10 minutes. After application, allow treated surfaces to air dry. Treat as required.

To Control Mold- and Slime-Forming Bacteria on Walls, Floors, Ceilings and Post-Crop Mushroom Growing Surfaces:

1. Preparation of solution: Per gallon of working solution mix, in a clean plastic container, 6 1/2 fl. oz. of SaniCide™-2 with 1 gallon of clean potable water. This will yield a working solution containing 1,000 ppm available chlorine dioxide.

2. To apply: During application treatment area must be closed as tightly as possible and sealed. Drench, spray or fog solution on walls, floors, ceilings and post-crop mushroom growing surfaces using a suitable watering, spraying or fogging device, making sure all surface areas are thoroughly wet. After spraying or fogging, open the treatment area and ventilate for 1 hour before re-entry. Allow all treated surfaces to air dry. Avoid contact with food or food contact surfaces. Repeat application as needed.

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To Control the Buildup of Odor- and Slime-Forming Bacteria in Process Waters for Vegetable Rinses and Associated Tanks, Flumes and Lines:

1. Preparation of solution: Prepare SaniCide™-2 solutions daily. Chill tanks or vegetable rinse tanks may be batch-loaded at startup with 1/3 fl. oz. (10 ml) SaniCide™-2 per 10 gallons of potable water. This will yield a working solution containing 5 ppm available chlorine dioxide. Treat make-up waters with a chemical feed pump or injector system and apply SaniCide™-2 at the rate of 1/3 fl. oz. per 10 gallons of potable water.
2. Optional activated solution: If heavy use of rinse water is expected or if slime buildup is extreme, an additional activation step may be used in preparation of the solution.
3. Preparation of activated solution: For each 10 gallons of rinse water to be used mix, in a clean plastic container, 1/3 oz. (10 ml) of SaniCide™-2 with 1 gallon of water and 8 grams (1/4 oz.) of DRA-1 (or 4 grams (1/8 oz.) of DRA-2). Allow this solution to stand for 15 minutes then add 9 gallons of water to yield a solution containing 5 ppm available chlorine dioxide.
4. Chill tanks or vegetable rinse tanks may be batch-loaded at startup with activated SaniCide™-2 solution by mixing 1/3 fl. oz. (10 ml) SaniCide™-2 with 10 gallons of potable water. This will yield a working solution containing 5 ppm available chlorine dioxide. Treat make up waters with a chemical feed pump. To ensure accurate delivery, prepare a 1 to 10 dilution of the active concentration and maintain the feed rate of this dilution at 3-1/3 fl. oz. per 10 gallons.

For Use in the Preparation of Fruits and Vegetables to Extend Freshness and Shelf-Life:

1. Wash whole fruits and vegetables then rinse with clean potable water.
2. To 1 gallon of water add 1/3 fl. oz. (10 ml) of SaniCide™-2 and 1 gram of DRA-1, or adjust the pH to 4 with vinegar. Allow solution to stand for 15 minutes then add to 9 gallons of water.
3. As a pretreatment for uncut, unpeeled fruits and vegetables, dip produce in solution for approximately 10 to 20 seconds, then rinse with potable water.

Biological Control in Paper Mills, Food Processing Flumes, Water Treatment Equipment, Petroleum Recovery, Hospital Disinfecting, Cutting Oils, Cooling Towers, Hard Surface Disinfection/Sanitation of Food Processing Equipment
Product Data

To Disinfect Walls, Ceilings and Floors:

1. Add 2.5 fl. oz. of SaniCide™-2 per gallon of solution to be used (1:51 dilution). Adjust the pH of the solution to 4 with acetic acid (vinegar), citric acid, phosphoric acid or add 1/2 up to 1/2 (0.25 up to 0.5) grams of DRA-2 to each gallon of solution. Allow to stand for 15 minutes.
2. Spray or fog the above solution onto surfaces to be disinfected. Allow surfaces to remain wet for at least 20 minutes then air dry. Apply only freshly prepared solutions.
3. For sink soaking of previously cleaned utensils, heavily stained dishes, glasses and equipment parts, prepare the solution as described above. Fill and hold for 20 minutes. Drain and air dry.

To Control the Buildup of Odor and Slime and Improve Taste in Ice Plants and Poultry/Meat Processing Plant Water:

1. Thoroughly clean ice making machinery with a detergent solution followed by a potable water rinse.
2. Meter into the incoming water to the ice plant potable water system 1 gallon of SaniCide™-2 per 1,000 gallons of water (20 ppm available chlorine dioxide).
3. As an additive to potable water in meat and poultry processing plants to inhibit bacterial slime and improve taste and odor, add 1 gallon of SaniCide™-2 per 1,000 gallons of water.

To Control Odor- and Slime-Forming Bacteria, Mold and Mildew on Walls, Floors and Ceilings:

1. Dilute 2.5 gallons of SaniCide™-2 to 20 gallons water (2,500 ppm available chlorine dioxide). Spray or soak the walls, floors and ceilings with this solution. Allow to air dry and repeat as necessary. Avoid contact with food.

To Inhibit Bacterial Slime-Forming Bacterial Buildup in Commercial Water Filtration Systems, Sand Beds, Gravel Beds, Charcoal Filters and Cooling Water Systems:

Filters:

1. Carefully back flush filters with potable water, where possible, to remove all accumulated solid residue and contamination.
2. Fill system with potable water and adjust the pH to 6.0 with citric acid, phosphoric acid or acetic acid (vinegar).
3. Add 2 fl. oz. of SaniCide™-2 per gallon of filter system volume (300 ppm) to the accumulation tank and circulate the system for 1 hour. Check the pH and adjust back to 6.0 if it has drifted. Bring the chlorine dioxide concentration back to 300 ppm.
4. Circulate the solution for 1 additional hour, discharge and then water wash for 30 minutes with potable water to remove the chlorine dioxide.

Cooling Water Systems:

1. Weekly, add 2.5 gallons of SaniCide™-2 per 10,000 gallons of cooling water.
2. Depending upon the degree and type of contamination, addition frequency may be reduced to every 2 to 3 weeks when contamination is under control.

In Industrial Applications to Inhibit the Growth of Slime- and Odor-Causing Bacteria in Water-Based Cutting Oils:

1. Batch Method: Add 80 fl. oz. of SaniCide™-2 per 1,000 gallons to fresh systems and repeat weekly or at first indication of increased bacterial contamination (odor, slime, bacterial count). Alkaline systems may require a higher concentration of SaniCide™-2.
2. Continuous Method: Proportion in 5 gallons of SaniCide™-2 per million gallons per day used in the system. Alkaline systems may require a higher concentration of SaniCide™-2.
3. Badly Contaminated Systems: Slug dose system with 25 gallons of SaniCide™-2 per million gallons of cutting oil. Then start the continuous procedure described above.
4. Adjust quantities in any of the above systems to compensate for levels of contamination, pH, type of contamination, etc. as necessary.

To Prevent Corrosion and Slime Bacteria in Oil Wells During Secondary Recovery Operations:

1. Prepare a working solution of 5,000 ppm stabilized chlorine dioxide by diluting each gallon of SaniCide™-2 used to 4 gallons solution with the injection water.
2. Proportion 1 part of the above solution into each 150 parts of reinjected acidified (3.0 to 4.0 pH) water.
3. Monitor microbial content of the water and increase or decrease the addition rate of the working solution as necessary.

In Food Processing Plants (Poultry, Meat, Fish), Dairies and Bottling Plants:

For use as a terminal food contact surface sanitizing rinse conforming to 21 CFR 178.1010(b)(34) and (c)(29) not requiring a subsequent potable water rinse.

1. This solution is intended for use as a food contact surface sanitizer for dairies, ice cream factories and food processing plants.
2. This solution may be used on hard surfaces such as tables, trays, bins, etc. and the interior or exterior of food processing equipment.
3. Thoroughly clean all equipment to remove gross food particles and soil by a pre-flush, pre-scrape and, where necessary, a pre-soak treatment. Clean surfaces or objects with a detergent or cleaner followed by a potable water rinse prior to applying sanitizing solution.
4. The active biocide in the system is free chlorine dioxide, even though the stabilized chlorine dioxide at pH 8.5 is mildly bacteriostatic. Free chlorine dioxide is released by the addition of an activator and/or acidulant. Prepare a solution containing 1,000 ppm of total available chlorine dioxide by adding 2.5 gallons of SaniCide™-2 per 50 gallons of water and 64 grams (2.3 ounces) of DRA-2. Agitate 5 minutes and allow to stand for 15 minutes. Alternatively, activate the solution by adding food grade citric acid, phosphoric acid or acetic acid (vinegar) to pH 4.0. Dilute 1 part of this solution with 4 parts water to provide 200 ppm total chlorine dioxide and approximately 125 ppm free chlorine dioxide (30 to 40 ppm free chlorine dioxide, when acid activation is used).

5. Allow this solution to contact all food processing equipment for at least 1 minute, but preferably longer, by transferring and/or spraying into each food processing vessel. It is essential that the sanitizing solution contact all surfaces to be sanitized; thus, fill hard to reach in-place equipment, pipes, closed vessels, etc. with the solution to ensure contact of all surfaces with the sanitizing solution.

6. After the required contact time (or longer), allow solution to drain from all surfaces and air dry.

7. The above solution may not be reused for sanitizing but may be diluted 1:5 with water and used for cleaning plant walls, floors and drains.

As a Slimecide in Paper Mills to Prevent Slime, Tar Spots and Pitch Spots in White Water Systems:

By maintaining a chlorine dioxide atmosphere in the white water the microorganisms cannot produce the nodules that result in slime.

1. If the pH of the white water is below 7.0, add 11 1/4 gallons of SaniCide™-2 per hundred tons of paper produced.

2. If the pH of the white water is above 7.0, then add 1/2 gallon of 50% sodium hypochlorite as an activator with each 11 1/4 gallons of SaniCide™-2.

3. For best results continuously proportion the SaniCide™-2 feed. In many cases, the SaniCide™-2 amount may be reduced after the system is clean.

Storage and Disposal

Do not contaminate water, food or feed by storage or disposal.

Storage: Do not store with easily oxidizable materials, acids, reducers or combustible materials. Avoid heat or freezing conditions. Store upright and do not stack drums over two high on pallets or partially filled drums. Use of a drum pump is suggested. Keep drum tightly closed when not withdrawing liquid. In case of spills, dilute with large quantities of water. Do not allow liquid to dry; this could present a fire hazard. Store only in original container and take care to prevent cross-contamination with fertilizers, food, feed or other pesticides.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label directions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Triple rinse (or equivalent), then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration; or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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