

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

February 5, 2015

Kim Davis Consultant/Agent RegWest Company, LLC ConSeal International, Inc. 90 Kerry Place, Suite 2 Norwood, MA 02062

Subject: Label Amendment – To add claim for Poultry Drinking Water Product Name: SaniCide®-2 EPA Registration Number: 58300-19 Application Date: November 6, 2014 Decision Number: 497771

Dear Ms. Davis:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

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Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Wanda Henson by phone at (703) 308-6345, or via email at <u>henson.wanda@epa.gov</u>

Sincerely,

Warder A. Dr. you

Demson Fuller, Product Manager 32 Regulatory Management Branch II Antimicrobials Division (7510P) Office of Pesticide Programs

Enclosure

	ACCEPTED	
SaniCide ^{®-} 2	02/05/2015	
2% Aqueous Stabilized Chlorine Dioxide	Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under	
Mushroom and Vegetable Rinse Applications Disinfectant/Deodorizer/Slimicide	EPA Reg. No. 58300-19	

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

For Institutional or Industrial Use

Active Ingredient:

Chlorine Dioxide	2%
Other Ingredients	
Total	100%

Keep Out of Reach of Children CAUTION

See side panel for First Aid and additional Precautionary Statements.

EPA Reg. No. 58300-19

EPA Est.

Net Contents: _____ gal [oz] {5 through 55 gals}

SaniCide[®] is a Registered Trademark of ConSeal International, Inc.

{Side Panels}	Sufforder 15 a Registered Hademark of Consear International, inc.
{Side Parleis}	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 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	Take off contaminated clothing.
or Clothing:	 Immediately rinse skin with plenty of water for 15-20 minutes.
	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.
Have the product	container or label with you when calling a poison control center or doctor or when going for
treatment. [You may also contact {phone number} for emergency medical treatment information.]	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

{Note: The First Aid statements' grid format will be used only if market label space permits; otherwise a paragraph format will be used.}

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 and before eating, drinking, chewing gum, using tobacco or using the toilet.

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.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product may be applied only by the methods specified on the labeling.

Product 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, Poultry Drinking Water 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 disinfectant/sanitizing solutions: Solutions may be irritating when inhaled. During spraying 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 ConSeal.

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 3¼ 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:

- Preparation of active disinfecting solution: Per gallon of working solution mix, in a clean plastic container, 3¼ 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, 6½ 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 or spray solution on walls, floors, ceilings and post-crop mushroom growing surfaces using a suitable watering spraying device, making sure all surface areas are thoroughly wet. After spraying or drenching, 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.

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

- 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.

Poultry To Treat Poultry Drinking Water Product Data

To Control Bacteria, Taste and Odor in the Water Supply System:

- 1. If the water supply is badly fouled with biofilm, add 5 ppm of available chlorine dioxide to the water supply by adding 1 part of SaniCide[®]-2 to each 4,000 parts of poultry drinking water.
- 2. After 24 hours the addition rate may be reduced to 1 ppm of available chlorine dioxide by adding 1 part **SaniCide®-2** to each 20,000 parts of poultry drinking or cooling comfort water.
- 3. If the microbiological content of the water is eliminated by this rate of addition, the concentration of available chlorine dioxide may be reduced to 0.5 ppm (1 part of SaniCide[®]-2 per 40,000 parts of water). If the microbiological control is not adequate at 1 ppm available chlorine dioxide add 1.5 ppm of available chlorine dioxide to the poultry drinking or cooling comfort water (1 part of SaniCide[®]-2 per 14,000 parts of 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:

- 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 ¼ up to ½ (0.25 up to 0.5) grams of DRA-2 to each gallon of solution. Allow to stand for 15 minutes.
- 2. Spray 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, and 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 Slimicide 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 11¹/₄ gallons of SaniCide[®]-2 per hundred tons of paper produced.
- 2. If the pH of the white water is above 7.0, then add ½ gallon of 50% sodium hypochlorite as an activator with each 11¼ 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.

Pesticide 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:** Non-refillable container; do not reuse or refill this container. Triple rinse (or equivalent) container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its end and tip it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Repeat this procedure two more times.

{Per PR Notice 2007-4 the batch code/lot number will appear on the label or container.}

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. To the extent consistent with applicable law, 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.



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.

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

[] Denotes alternate/optional language

{ } Denotes language that does not appear on the market label.