58300-18 11-02-2011 1/7

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 2, 2011

FILE COPY

Kim Davis
Consultant/Agent,
ConSeal International, Inc.,
c/o RegWest Company LLC
8203 West 20th St., Suite A, Greeley, CO 80634-4696

Subject: Sanicide®-20
EPA Registration No. 58300-18
Application Dated: August 12, 2011
Receipt Dated: August 15, 2011

Dear Ms. Davis:

This acknowledges the receipt of your Amendment application dated August 12, 2011 in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, is acceptable with comments.

Submission and Proposed Changes

Add the Agent address on the CSF of Sodium Hypochlorite Solution (EPA Reg#. 33981-20001) and with no changes to the formulation itself.

General Comments

This submitted application change is acceptable with the following comments (see ARTCA -Antimicrobial Regulation Technical Corrections Act of 1998 (Pub. L. 105-324) ***http://www.access.gpo.gov/nara/publaw/105publ.html***

1. P3. Move the "Directions for Use in Controlling Microbial Population in Poultry Processing Water:" statement as a subheading under "Food Plant Process Water Treatment:" to read a: **Controlling Microbial Population in Poultry Processing Water**
For treatment of poultry chill water, apply SaniCide-20 as necessary through a chlorine dioxide generation system to maintain a residual concentration of up to 3 ppm chlorine dioxide in the chiller water. Chlorine dioxide in poultry-processing water generated from Sanicide®-20 product may be used for poultry processing, but must comply with the US FDA regulation 21 CFR § 173.300.

2. P3. Change "Water, containing up to 3 ppm residual chlorine dioxide may be used for washing fruits and vegetables that are not raw agricultural commodities in accordance with 21 CFR § 173.300.", statement to read:

b: **Controlling Microbial Population in Fruit and Vegetable Wash Water**
For treatment of fruit and vegetable wash water, apply SaniCide®-20 as necessary through a Chlorine dioxide generation system to maintain a residual concentration of up to 3 ppm chlorine dioxide in the wash water. Chlorine dioxide in fruit and vegetable processing water generated from Sanicide®-20 product may be used for fruit and vegetable that are not raw agriculture commodities (RAC), but must comply with the US FDA regulation 21 CFR § 173.300.

This amendment and a copy of this letter have been inserted in your file for future reference

If you have any questions or comments concerning this letter, please contact liem.david@epa.gov or call (703) 305-1284.

Sincerely,

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

Enclosure: Stamped label

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SaniCide®-20

[{Select marketing claims from "Marketing Claims" section below}]

ACCEPTED
with COMMENTS
in EPA Letter Dated:

NOV - 2 2011

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 58300-18

Active Ingredient:	
Sodium Chlorite (CAS No. 7758-19-2)	25%
Other Ingredients	75%
Total	100%

Keep Out of Reach of Children

DANGER

See side [back] panel for First Aid and additional Precautionary Statements.

EPA Reg. No. 58300-18 **EPA Est. 58300-MA-1**

Net Contents: _____ gals [fl oz.]
{1, 5 or 55 gallons}

{Side Panel [Back Panel]}

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. • Immediately rinse skin with plenty of water for 15-20 minutes. • 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 the poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If Inhaled:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably 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 going for treatment.	
Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.	

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

PRECAUTIONARY STATEMENTS

Hazards to Humans & Domestic Animals

DANGER: Highly Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. Irritating to nose and throat. Do not get in eyes, on skin or clothing. Wear protective eyewear (goggles or safety glasses), protective clothing and rubber gloves when handling this product. Avoid breathing dust and fumes. Thoroughly wash with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Physical or Chemical Hazards

Dry sodium chlorite is a strong oxidizing agent. This product becomes a fire or explosive hazard if allowed to dry. Mix only into water. Contamination may start a chemical reaction with generation of heat, liberation of hazardous gases

(chlorine dioxide – a poisonous, explosive gas) and possible fire and explosion. Do not contaminate with garbage, dirt, organic matter, household products, chemicals, soap products, paint products, solvents, acids, vinegar, beverages, oils, pine oil, dirty rags or any other foreign matter.

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 waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to the discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local 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.

Directions for Controlling the Growth of Algae in Recirculating Cooling Water Towers:

1. Clean badly fouled systems before starting treatment.
2. When algae are visible, add an initial dosage of 8.4 fluid ounces of **SaniCide®-20** per 1,000 gallons of water in the system. Repeat if necessary until control is evident.
3. Where algae control is evident, use a subsequent dose of 4.2 fluid ounces of **SaniCide®-20** per 1,000 gallons of water in the system twice a week or as needed to maintain control.
4. Add **SaniCide®-20** directly to the cooling tower drip pan (cold water basin) near the inlet to the recirculating pump.

Directions for Use in the Mechanical or Electrolytic Generation of Chlorine Dioxide (ClO_2) as a Disinfectant, or for Microorganism or Mollusk Control and as a Chemical Oxidant in Aquatic Systems:

Feed Requirements: Feed rates of **SaniCide®-20** will depend on the severity of contamination and the degree of desired control. The exact dosage will depend on the size of the system and residual necessary for effective control. Depending on the generator type, **SaniCide®-20** may be diluted at the point of use to prepare a 3% to 25% active aqueous solution for use in chlorine dioxide generators.

Some examples of industrial applications of chlorine dioxide include:

- Potable water disinfection and removal of sulfide.
- Control of bacterial slime, algae and mollusks in industrial recirculating and one-pass cooling systems.
- Biocontrol in food processing flumes, water-using equipment, cooling water and recycled waters.
- Disinfection of sewage and plant wastes.
- Destruction of phenolics, simple cyanides and sulfides by chemical oxidation.
- Bacterial slime control in white water paper mill systems.
- Bacterial control in oil well and petroleum systems.

See product bulletins (or Technical Data Sheets) for specific application instructions. Your ConSeal International representative can guide you in the application techniques.

Method of Feed: Large amounts of chlorine dioxide can be generated by several common methods, including:

1. The chlorine method that utilizes a Sodium Chlorite solution and chlorine gas; or
2. The hypochlorite method that utilizes a Sodium Chlorite solution, a hypochlorite solution and an acid; or
3. The Acid-chlorite method that utilizes a Sodium Chlorite solution and an acid; or
4. The electrolytic method that utilizes a Sodium Chlorite solution, with sodium chloride added as needed.

Your ConSeal International representative can guide you in the selection, installation and operation for feed systems. Consult product bulletin and also the instructions on the chlorine dioxide generation system before using **SaniCide®-**

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20. User is responsible for compliance with applicable Federal, state and local laws/regulations regarding proper use and disposal of the chlorine dioxide generated.

Directions for Use in Controlling Microbial Population in Poultry Processing Water:
Chlorine dioxide generated from **SaniCide®-20** may be used as an antimicrobial agent in poultry-processing water, provided that the residual concentration of chlorine dioxide does not exceed 3 parts per million (ppm), as determined by an appropriate method in accordance with 21 CFR § 173.300. For treatment of poultry chill water, apply **SaniCide®-20** as necessary through a chlorine dioxide generation system to maintain a residual concentration of up to 3 ppm chlorine dioxide in the chiller water.

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Food Plant Process Water Treatment:
Chlorine dioxide generated from sodium chlorite is effective for use in controlling microbiological growth in flume water and other food processing water systems such as chill water systems and hydrocoolers. The required dosages will vary with process conditions and the degree of contamination present. Depending on the requirements of the specific water system, apply sodium chlorite continuously or intermittently through a chlorine dioxide generating system to achieve a chlorine dioxide residual concentration between 0.25 and 5 ppm.

(a) Controlling Microbial Population in Poultry Processing Water
Water, containing up to 3 ppm residual chlorine dioxide may be used for washing fruits and vegetables that are not raw agricultural commodities in accordance with 21 CFR § 173.300. Treatment of the fruits and vegetables with chlorine dioxide must be followed by a potable water rinse, or by blanching, cooking or canning.

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(b) Controlling Microbial Population in Fruit and Vegetable Wash Water

Industrial Cooling Water Treatment
For control of bacterial slime and algae in industrial recirculating and one-pass cooling systems, the required dosages will vary depending on the exact application and the degree of contamination present. The required chlorine dioxide residual concentrations range between 0.1 and 5 ppm. Chlorine dioxide may be applied either continuously or intermittently. The typical chlorine dioxide residual concentration range is 0.1 to 1 ppm for continuous doses and 0.1 to 5 ppm for intermittent doses. The minimum acceptable residual concentration of chlorine dioxide is 0.1 ppm for a minimum one-minute contact time.

Potable Water Treatment:
Chlorine dioxide is used as both an oxidant and a disinfectant in drinking water treatment. The required dosages will vary with source water conditions and the degree of contamination present. For most municipal and public potable water systems, a chlorine dioxide residual concentration of up to 2 ppm is sufficient to provide adequate disinfection. Residual disinfectant and disinfection byproducts must be monitored as required by the National Primary Drinking Water Regulations (40 CFR Part 141) and state drinking water standards.

Bacterial Slime Control in Paper Mills:
Chlorine dioxide generated from sodium chlorite is effective for use in controlling microbiological growth in white water paper mill systems. The required dosages will vary with the degree of microbiological and process contamination present. Depending on the specific requirements of the system, apply sodium chlorite continuously or intermittently through a chlorine dioxide generating system to achieve a chlorine dioxide residual concentration between 0.1 and 5 ppm. Repeat intermittent treatments as often as necessary to maintain control.

Mollusk Control in Water Systems:
Chlorine dioxide generated from sodium chlorite may be used for mollusk control in commercial and industrial recirculating and one-pass cooling water systems. The required dosages will vary with the system type and conditions, the degree of water contamination present and the desired level of control. Depending on the extent of the infestation, sodium chlorite may be applied either continuously or intermittently through a chlorine dioxide generating system to achieve the necessary chlorine dioxide residual concentration.
Veliger Control: Maintain a continuous chlorine dioxide residual of 0.1 to 5 ppm.

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Intermittent Dose: Apply chlorine dioxide to obtain a chlorine dioxide residual concentration of 0.2 to 25 ppm. Repeat as necessary to maintain control.
Continuous Dose: Maintain a chlorine dioxide residual concentration of up to 2 ppm.

Bacterial Control in Oil Wells and Petroleum Systems:
Chlorine dioxide is effective in the remediation of bacterial and sulfide contamination commonly found in oilfield production, injection and disposal fluids. The required dosages will vary with process conditions. Sodium chlorite may be applied either continuously or intermittently through a chlorine dioxide generating system to oil well production water as it is separated from the oil and before it is re-injected into the well.

For continuous feeds, chlorine dioxide may be applied at dosages slightly higher than sulfide's oxidative demand as determined by a demand study. For intermittent treatment, apply chlorine dioxide at a shock dosage of 200 to 3,000 ppm.

Wastewater Treatment:
Chlorine dioxide is effective as both a disinfectant and an oxidant in wastewater treatment. The required dosages will vary with water conditions and the degree of contamination present. For most municipal and other wastewater systems, a chlorine dioxide residual concentration of up to 5 ppm is sufficient to provide adequate disinfection.

For sulfide odor control, between pH 5 to 9, apply a minimum of 5.2 ppm (wt) of chlorine dioxide to oxidize 1 ppm of sulfide (measured as sulfide ion). For phenol destruction, at pH less than 8, 1.5 ppm chlorine dioxide will oxidize 1 ppm phenol; at pH greater than 10, 3.3 ppm chlorine dioxide will oxidize 1 ppm phenol.

{For rigid non-refillable containers less than or equal to 5 gallons}

Storage and Disposal

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

Pesticide Storage: Keep product in tightly closed container when not in use. Don't drop, roll or skid container. Keep upright. Always replace cover. Store in a cool, dry, well-ventilated area away from heat or open flame. **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 instructions, contact your state pesticide or environmental control agency or the hazardous waste representative at the nearest EPA regional office for guidance. **Container Management/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 and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow beings to drip. Repeat this procedure two more times. Offer for recycling, if available, or reconditioning if appropriate; or puncture and dispose of in a sanitary landfill; or by incineration; or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

{For rigid non-refillable containers greater than 5 gallons}

Storage and Disposal

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

Pesticide Storage: Keep product in tightly closed container when not in use. Don't drop, roll or skid container. Keep upright. Always replace cover. Store in a cool, dry, well-ventilated area away from heat or open flame. **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 instructions, contact your state pesticide or environmental control agency or the hazardous waste representative at the nearest EPA regional office for guidance. **Container Management/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 closure. Tip container on its side and roll 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. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Offer for recycling, if available, or reconditioning, if appropriate; or puncture and dispose of in a sanitary landfill; or by incineration; or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

{For refillable containers}

Storage and Disposal

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

Pesticide Storage: Keep product in tightly closed container when not in use. Don't drop, roll or skid container. Keep upright. Always replace cover. Store in a cool, dry, well-ventilated area away from heat or open flame. **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 instructions, contact your state pesticide or environmental control agency or the hazardous waste representative at the nearest EPA regional office for guidance. **Container Management/Disposal:** Refillable container. Refill this container only with sodium chlorite; do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean this container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10% full with water. Agitate vigorously or recirculate water with a pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure 2 more times. Offer for recycling if available, or reconditioning if appropriate; otherwise, discard in the trash[or dispose of in a sanitary landfill].

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

Notice: Seller expressly warrants that this product conforms to its chemical description. To the extent permitted by 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

{Marketing Claims}

For Industrial Use
Algaecide
Molluskicide
Antimicrobial/Disinfectant

{End of Marketing Claims}

[ ] Denotes alternate/optional language
{ } Denotes language that does not appear on the market label.