



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

AUG 29 2013

Mrs. Kimberlee Young, Agent For: ConSeal International, Inc.
ConSeal International, Inc.
c/o RegWest Company, LLC
8203 West 20th Street, Suite A
Greeley, CO 80634-4696

Subject: Label Amendment per Agency Letter Dated April 1, 2013
SaniCide™-5
EPA Registration Number: 58300-16
Application Date: May 31, 2013
EPA Receipt Date: June 3, 2013

Dear Mrs. Young:

The following amendment, submitted pursuant to registration under Federal Insecticide Fungicide and Rodenticide Act (FIFRA) 3(c) 5, as amended.

Amendment Purpose:

WE are electing to delete from the Product Label all references to "fogging" and adding the phrase "This product may be applied only by methods specified on the labeling."

Review Results:

On Page One:

Deleting the NSF Logo.

Inserting the sentence, "This product may be applied only by methods specified on the labeling."

On Page Two:

Deleting "or fogging" twice in Item No. 4 of the Product Information subsection that begins on Page One.

Deleting "or fog" and "or fogging" and "drenching fogging" in Item No. 3 of the "To Control Mold- and Slime-Forming Bacteria on Walls, Floors, Ceilings and Post-Crop Mushroom Growing Surfaces" subsection.


All references to "fogging" on the Product Label are deleted.

General Comments:

Based on the review of the information submitted, the following comments apply. The Label Amendment is Acceptable. An EPA-stamped, Accepted Product Label is enclosed for your Company record. And a copy of the EPA-stamped, Accepted Product Label is attached in Regulatory File Jacket 58300-16 for future reference.

If you have questions or comments with regard to this Agency Letter, please contact Killian Swift by email at Swift.Killian@epa.gov or by telephone at 703-308-6346. 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,
Acting EPA Product Manager 32
Regulatory Management Branch II
Antimicrobials Division 7510P

Enclosure: EPA-stamped, Accepted "SaniCide™ -5" Product Label.

SaniCide™-5

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

For Institutional or Industrial Use

Active Ingredient:	
Chlorine Dioxide	5%
Other Ingredients	<u>95%</u>
Total	100%

ACCEPTED
 AUGUST 29, 2013
 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 58300-16

Keep Out of Reach of Children

CAUTION

See side panels for First Aid and additional Precautionary Statements.

EPA Reg. No. 58300-16 EPA Est. _____



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 [ounces]
{1 pint through 55 gallons}

ConSeal International, Inc.

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Norwood, MA 02062
(781) 278-0010
info@consealint.com

SaniCide™ is a Trademark of ConSeal International, Inc.

{Side Panels}

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

1. Refer to **Product Data** section before using this product in the generation of chlorine dioxide for biological control in Mushroom/Vegetable Processing/Canning operations, in Animal Rearing/Confinement facilities and Water Storage Systems
2. 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.
3. When preparing activated solutions: Prepare only in well-ventilated area. Avoid breathing any fumes that may be 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.

4. 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.

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 1-1/3 fl. oz. of **SaniCide-5** concentrate with 5 gallons of clean potable water and 1.2 grams of DRA-1 (or 10 grams of DRA-2). 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. 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. Preparation of active disinfecting solution: Per gallon of working solution mix, in a clean plastic container, 1-1/3 fl. oz. of **SaniCide-5** concentrate with 1 gallon of clean potable water and 1.2 grams of DRA-1 (or 8.6 grams of DRA-2). This will yield a working solution containing 500 ppm available chlorine dioxide.
3. To apply: Spray disinfectant solution onto surface 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. 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. Preparation of solution: Per gallon of working solution mix, in a clean plastic container, 2-2/3 fl. oz. of **SaniCide-5** concentrate with 1 gallon of clean potable water. This will yield a working solution containing 1,000 ppm available chlorine dioxide.
3. 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 or 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.
4. 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:

1. Preparation of solution: Prepare **SaniCide-5** solutions daily. Chill tanks or vegetable rinse tanks may be batch-loaded at startup with 1/3 fl. oz. (10 ml) **SaniCide-5** per 25 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-5** at the rate of 1/3 fl. oz. per 25 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 25 gallons of rinse water to be used mix, in a clean plastic container, 1/3 fl. oz. (10 ml) of **SaniCide-5** with 1 gallon of water and 0.002 grams of DRA-1 (or 2.2 grams of

DRA-2). Allow this solution to stand for 15 minutes then add 24 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-5** by mixing 1/3 fl. oz. (10 ml) **SaniCide-5** with 25 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 25 gallons. Prepare fresh **SaniCide-5** solutions daily.

Animal Rearing and Confinement Facilities: Hard, Non-Porous Surfaces

Product Data

To Disinfect Commercial Animal Confinement Facilities such as Poultry Houses, Swine Pens, Calf Barns and Kennels:

1. Remove all animals, poultry and feed from premises, vehicle enclosures, coops and crates.
2. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals.
3. Empty all troughs, racks and other feeding and watering appliances.
4. Thoroughly clean all surfaces with soap or detergent, then rinse with water.
5. Preparation of active disinfectant solution: In a clean plastic container mix 1-1/3 fl. oz. **SaniCide-5** concentrate with 1 gallon clean potable water and 1.2 grams of DRA-1 (or 1/4 to 1/2 (0.25 to 0.5) grams of SaniCide DRA-LT). This will yield a working solution containing 500 ppm available chlorine dioxide. Prepare in a well-ventilated area and avoid breathing any fumes which may be produced during activation.
6. To apply: Using a commercial sprayer, saturate all surfaces with the activated **SaniCide-5** solution for a period of 10 minutes. Immerse all halters, ropes and other types of equipment used in handling and restraining animals in addition to forks, shovels and scrapers used for removing litter and manure.
7. After treatment, ventilate building, coops and other enclosed spaces and allow to air dry. Do not allow animals or poultry to re-enter the treated area until solution has dried.
8. Thoroughly scrub treated feed racks, troughs, automatic feeders, fountains and waterers with soap or detergent and rinse with potable water before use.

Drinking Water for Cattle, Poultry, Swine and Other Livestock

To Control Taste and Odor in the Water Supply System:

1. Prepare a solution with 5 ppm available chlorine dioxide by adding 1 part **SaniCide-5** to 10,000 parts water (a 1:10,000 dilution) (1 fl. oz. **SaniCide-5** per 75 gallons). Allow 15 minutes before delivery to livestock or poultry.
2. If the water supply has heavy contamination, prepare a solution of 11 ppm available chlorine dioxide by adding 1 part **SaniCide-5** to 4,545 parts water (a 1:4,545 dilution) (1 fl. oz. **SaniCide-5** per 35.5 gallons). Allow 15 minutes before delivery to livestock or poultry.
3. After 24 hours, reduce the addition rate to 1 ppm available chlorine dioxide by adding 1 gallon of **SaniCide-5** to each 50,000 gallons of animal drinking water, provided the terminal concentration at the end of the waterline is not less than 0.5 ppm.
4. Continuously treat the water from day one. Remove **SaniCide-5** from drinking water 24 hours prior to vaccinations, then resume treatment 24 hours after vaccinations. **Note:** *This product is not intended for use in human drinking water and treated water must not be made available for human consumption.*

To Disinfect Drinking Water Supply for Cattle, Poultry, Swine and Other Livestock:

Use **SaniCide-5** with a chlorine dioxide generator to generate an aqueous chlorine dioxide solution. Alternatively, **SaniCide-5** can be mixed manually to generate an aqueous chlorine dioxide solution. The chlorine dioxide generator and manual mixing methods react **SaniCide-5** with either a chlorine solution and acid or an acid. The generated chlorine dioxide solution can be added at a point in this system which ensures uniform mixing and distribution of up to 5 ppm of chlorine dioxide.

Carefully follow all instructions for the chlorine dioxide generator. Always prepare and use chlorine dioxide solutions in a well-ventilated area. Treat water continuously from day one. Remove **SaniCide-5** from drinking water 24 hours prior to vaccination, then resume treatment 24 hours after vaccinations.

Note: This is not intended for use in human drinking water and treated water must not be made available for human consumption.

1. Manual Mixing Method A

- A. For a 5 ppm chlorine dioxide solution add 1 part **SaniCide-5** concentrate to 10,000 parts water (1 fl. oz. of **SaniCide-5** per 80 gallons of water). Use more water for lower chlorine dioxide concentrations.
- B. Add 2-5 ppm sodium hypochlorite; 3-8 parts of 12.5% bleach to 10,000 parts water.
- C. Using an appropriate acid add sufficient acid to lower solution pH to 5.0-6.5.
- D. Allow 15 minutes before delivery to livestock water lines.
- E. After 24 hours, the addition rate can be reduced to 1 ppm of available chlorine dioxide by adding 1 fl. oz. of **SaniCide-5** concentrate to approximately 400 gallons of animal drinking water provided the terminal concentration at the end of the water line is not less than 0.5 ppm.

2. Manual Mixing Method B

- A. Add 1 part **SaniCide-5** concentrate to 9 parts water.
- B. Activate by adding phosphoric, hydrochloric, acetic or other food grade acid to a pH of 2.5-3.5.
- C. Mix and allow to stand for at least 15 minutes before delivery to livestock water lines.
- D. Dilute 1 part of the activated solution with 1,000-5,000 parts water for a 1-5 ppm chlorine dioxide solution.

To Control the Buildup of Odor- and Slime-Forming Bacteria in Animals' Confinement Areas:

1. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes, cases and other facilities and fixtures occupied or traversed by animals.
2. Preparation of solution: In a clean plastic container mix 2-2/3 fl. oz. of **SaniCide-5** concentrate with 1 gallon of clean potable water. This solution will yield 1,000 ppm available chlorine dioxide.
3. To apply: Using a commercial sprayer, saturate all surfaces with the **SaniCide-5** solution. When spraying, always use an applicable NIOSH-approved respirator appropriate for chlorine dioxide.

To Control Animal Odors on Pets and in Litter Boxes, Carpets and Concrete Floors:

1. **For litter boxes:** Wash empty litter boxes with a suitable detergent and rinse with clean potable water. Soak boxes overnight in a solution made by mixing 1 fl. oz. **SaniCide-5** concentrate with 2-1/2 quarts water. This will yield a solution containing 625 ppm available chlorine dioxide. Allow boxes to air dry before filling with clean litter. Add litter and liberally sprinkle the litter surface with the **SaniCide-5** solution.
2. **For controlling odors in carpets:** Mix 1-1/4 fl. oz. **SaniCide-5** in 1 gallon rug shampoo solution or 1 gallon rinse water. This will yield a solution containing 500 ppm available chlorine dioxide. Shampoo carpets and allow to air dry. **Note:** **SaniCide-5** may bleach some carpets and fabrics, especially if applied on top of another chemical agent. Do not make general application until a small sample, in an inconspicuous area, has been treated and observed for at least 24 hours.
3. **For concrete floors:** Thoroughly clean floor using a suitable detergent, then rinse with clean water. Mix 3-1/4 fl. oz. **SaniCide-5** concentrate with 1 gallon of water. This will yield a solution containing 1,300 ppm available chlorine dioxide. Mop or liberally spray solution onto floor and allow to air dry.
4. **For animal baths:** Wash animal with an appropriate pet shampoo and rinse with clean water. Prepare solution by mixing 1/4 fl. oz. **SaniCide-5** concentrate with 1 gallon water. This will yield a solution containing 100 ppm available chlorine dioxide. Thoroughly rinse animal with solution and allow to air dry. Do not allow solution to contact animals' eyes, nose or ears.
5. **For treating animal odors with high levels of ammonia:** Thoroughly wash area to be treated with a suitable detergent and rinse with clean water. Preparation of solution: For each gallon of solution mix, in a clean plastic container, 1-2/3 fl. oz. **SaniCide-5** concentrate with 1 tablespoon household bleach. Allow this

solution to react for 5 minutes. Dilute with 1 gallon clean potable water. Apply by mopping or liberally spraying solution onto area. Allow to air dry. Additional applications may be necessary.

To Disinfect Nonporous Hard Surfaces such as Walls, Ceilings and Floors:

1. Preparation of active disinfecting solution: In a clean plastic container mix 1-1/3 fl. oz. of **SaniCide-5** concentrate with 1 gallon water and 1.2 grams DRA-1 (or 1/4 to 1/2 (0.25 to 0.5) grams of SaniCide DRA-LT). This will yield a working solution containing 500 ppm available chlorine dioxide.
2. To apply: Activated solution may be sprayed, mopped or sponged onto surfaces to be disinfected. All surfaces must be thoroughly wet for at least 10 minutes. Use an appropriate spraying device. After application, allow treated surfaces to air dry. Treat as required.

Treatment of Water Storage Systems

To Disinfect Water Storage Systems Aboard Aircraft, Boats, Buses, Off-Shore Oil Rigs, RVs, Trains, etc.:

1. Prior to disinfection, tanks must be cleaned using a suitable detergent and thoroughly flushed with clean, potable water.
2. Preparation of active disinfecting solution: In a clean plastic container mix 0.8 fl. oz. of **SaniCide-5** concentrate with 1 gallon water and 1.2 grams DRA-1 (or 1/4 to 1/2 (0.25 to 0.5) grams of SaniCide DRA-LT). Allow 15 minutes reaction time and for the activator to completely dissolve. This will yield a working solution containing 300 ppm available chlorine dioxide.
3. Pour activated solution into tank, filling the tank completely. Bleed air out of lines and allow to stand at least 10 minutes. Drain tank and lines and flush with potable water.

{For product in non-refillable containers 1 pint through 5 gallons;}

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 Management:** Nonrefillable 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 1/4 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 begins to drip. Repeat this procedure two more times, then offer for recycling, if available; or reconditioning, if appropriate; or puncture and dispose of in a sanitary landfill, or by incineration.

{For product packaged in non-refillable containers greater than 5 gallons:}

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 Management:** Nonrefillable 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 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, then offer for recycling, if available; or reconditioning, if appropriate; or puncture and dispose of in a sanitary landfill; or by incineration.

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

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

If Swallowed:	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • 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:	<ul style="list-style-type: none"> • 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.
<p>Have the product container or label with you when calling a poison control center or doctor or when going for treatment. For emergency information concerning this product, call the National Pesticide Information Center (NPIC) at 1.800.858.7378, seven days a week, 6:30 am-4:30 pm Pacific Time (NPIC website: www.npic.orst.edu).</p>	
<p>Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.</p>	

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

Physical and 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. 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.

{Marketing Claims}

5% Aqueous Stabilized Chlorine Dioxide
Animal Confinement Facilities Disinfectant/Deodorizer
Control Taste and Odor in Animal Confinement Facility Water Supply Systems
Disinfect Drinking Water Supply for Cattle, Poultry, Swine and Other Livestock
Mushroom and Vegetable Rinse Applications Hard, Non-Porous Surface Disinfectant Deodorizer
Mushroom and Vegetable Rinse Applications Disinfectant/Deodorizer
Poultry Houses, Swine Pens, Calf Barns and Kennels
Treatment of Water Storage Systems

{End of Marketing Claims}

[] Denotes alternate/optional language

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