

70299-9

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

NOV 18 2010

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

BioSafe Systems, LLC  
22 Meadow Street  
East Hartford, CT 06108

Attention: Donna Bishel  
Technical Director

Subject: Amendment – SaniDate Ready to Use – Add a supplemental organism  
EPA Reg. No. 70299-9  
Amendment Letter Dated August 30, 2010

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. The Agency approves the following Amendments to the label:

- Addition of the supplemental organism *Salmonella enterica* for food contact sanitization claims.

In addition, the following changes must be made to the label prior to the product going to market:

- The label lacks Use Directions to support the proposed deodorization claims. To support deodorization the proposed label must be revised to include directions for this use.
- The proposed claim, "Ready to Use treatment for healthier plants" is unacceptable. Claims that imply or suggest that the product can or will prevent or control disease or offer health protections are unacceptable.
- The proposed claims, "Kills 99.9% of bacteria that can cause food borne illnesses" and "Kills 99.9% of bacteria that can cause food poisoning" are misleading and must be removed. Additional bacteria not included on the proposed label may contribute to food illnesses and food poisoning.
- The provided efficacy data do not consistently support the claim, "Sanitizes while you clean." Efficacy data was not generated in the presence of organic soil load. This claim must therefore be removed.

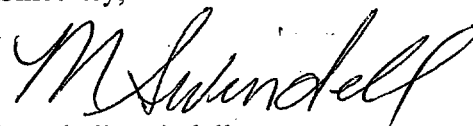
2 EPA Reg. No. 53735-11

- On the label the term “porcelain” must be revised to read “glazed porcelain” as porcelain is a porous surface.
- On the label the term “cutting boards” must be revised to read “non-wooden cutting boards.”

A stamped copy of the accepted labeling is enclosed. Submit three copies of your final printed labeling to the Agency before distributing or selling the product bearing the revised labeling.

If you have any questions concerning this letter, please contact Abigail Downs at (703) 305-5259.

Sincerely,



Marshall Swindell  
Product Manager (33)  
Regulatory Management Branch I  
Antimicrobials Division (7510P)



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## Sublabel A: Commercial Directions for Use

### SURFACE SANITATION

SANIDATE® Ready to Use is an effective sanitizer against gram positive and gram negative bacteria (vegetative forms): *Staphylococcus aureus* and *Klebsiella pneumoniae*.

Use this product in general commercial environments to clean, sanitize, and deodorize inanimate surfaces, such as:

- Floors, walls, and other non-porous surfaces such as tables, chairs, counter tops, garbage cans/bins, bathroom fixtures, sinks, bed frames, shelves, racks, carts, tools, equipment, exterior of refrigerators, coolers, tile, and use sites listed on this label made of linoleum, vinyl, porcelain, plastic (such as polyethylene), metal, stainless steel, or glass.
- Schools, colleges, industrial facilities, dietary areas, office buildings, recreational facilities, retail and wholesale establishments.
- Animal hospitals, veterinary clinics, animal life science laboratories, kennels, kennel runs, cages, feeding and watering equipment, pet shops, zoos, pet animal quarters, poultry premises, trucks, hatcheries and live stock quarters.
- Greenhouses, farms, nurseries

### SANITIZING FOOD CONTACT SURFACES

SANIDATE® Ready to Use is an effective sanitizer against *Staphylococcus aureus* (Staph), *Salmonella enterica* (Salmonella) and *Escherichia coli* (E. coli) on hard, non-porous food contact surfaces and equipment. Use this product to sanitize cutting boards, sinks, countertops, tabletops, trays, pans, racks, platters, cans, produce cases, pasteurizers, aseptic equipment, vats, and tanks. SANIDATE® Ready to Use is an effective sanitizer for use in the washing, rinsing and sanitizing of conveyor, boxing or packing equipment, peelers, corers, de-boners, scrapers, collators, slicers, dicers, knives, and saws.

Use this product in the following commercial environments to clean, sanitize, and deodorize food contact surfaces:

- Dairies, wineries, breweries, and beverage plants
- Packing houses, food processing plants and farms
- Meat, meat products, milk and dairy processing, packing, and rendering plants
- Seafood, poultry and egg processing/packing plants
- Fruit and vegetable processing/packing plants
- Grocery stores, supermarkets, food distribution and storage facilities
- Food service operations, eating establishments, restaurants, cafeterias, kitchens, food preparation areas
- Schools, office buildings, industrial facilities

### FRUIT AND VEGETABLE WASH

Use SaniDate® Ready to Use to clean fruits and vegetables. SaniDate® Ready to Use will help remove pesticide residues, chemicals, and soil, as well as spoilage and decay organisms on the surfaces of fruit and vegetables.

ACCEPTED  
With COMMENTS  
EPA Letter Dated:  
NOV 18 2010

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No.  
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Use this product to clean fruits and vegetables in the following commercial environments:

- Fruit and vegetable processing/packing plants
- Grocery stores, supermarkets, food distribution and storage facilities
- Eating establishments, restaurants, cafeterias
- Food preparation areas

**DIRECTIONS FOR USE**

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

**APPLICATION INSTRUCTIONS:**

**(For Spray Bottle)** Turn nozzle to "spray" or "stream". Spray 6 to 8 inches from surface.

**Sanitization of Hard, Non-Porous Surfaces**

To Sanitize: Remove gross filth. Pre-clean hard, non-porous surfaces to be treated with a recommended detergent, or with a cleaning treatment of SaniDate® Ready to Use. Spray until thoroughly wet; *do not dilute*. Let stand 5 minutes, and then air dry. No potable rinse is required.

**Sanitization of Hard, Non-Porous Food Contact Surfaces**

To Sanitize: Remove gross food particles. Pre-clean hard, non-porous surfaces to be treated with a recommended detergent, followed by a potable water rinse. Spray until thoroughly wet; *do not dilute*. Let stand 1 minute. If desired, wipe with paper towel or clean dish towel. Allow to air dry. Do not rinse.

**Fruit and Vegetable Treatment**

Fruit and Vegetable Wash: Rinse with clean water to remove excess soil. Spray all fruit or vegetable surfaces until wet with SaniDate® Ready to Use. Rub produce for 30-60 seconds. Thoroughly rinse produce under clean running water to remove soil and excess cleaner.

**APPLICATION INSTRUCTIONS:**

**(For 1 or 5 Gallon Container)** Pour required amount into bucket; *do not dilute*. Apply solution with a mop, cloth, sponge, brush, scrubber, or coarse spray device, or by soaking to completely immerse all surfaces to be treated.

**Sanitization of Hard, Non-Porous Surfaces**

To Sanitize: Remove gross filth. Pre-clean hard, non-porous surfaces to be treated with a recommended detergent or with a cleaning treatment of SaniDate® Ready to Use, and rinse well with potable water. Apply fresh solution to surface until thoroughly wet; *do not dilute*. Let stand for 5 minutes and then air dry. No potable rinse is required.

**Sanitization of Hard, Non-Porous Food Contact Surfaces**

To Sanitize: Remove gross food particles. Pre-clean hard, non-porous surfaces to be treated with a recommended detergent, followed by a potable water rinse. Apply SaniDate® Ready to Use to surface until thoroughly wet; *do not dilute*. Let stand 1 minute. If desired, wipe with paper towel or clean dish towel. Allow to air dry. Do not rinse.

**Fruit and Vegetable Treatment**

Fruit and Vegetable Wash: Pour solution into a container and let fruit and vegetables soak in the solution for a minimum of 30-60 seconds. Rub or swish as needed. Thoroughly rinse produce under clean running water to remove soil and excess cleaner.

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with COMMENTS

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**STORAGE AND DISPOSAL**

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

**Pesticide Storage:** Store in original containers in a cool, well-vented area, away from direct sunlight. Do not allow product to become overheated in storage. This may cause increased degradation of the product, which will decrease product effectiveness. In case of spill, flood area with large quantities of water.

**Pesticide Disposal:** Triple rinse container (or equivalent) 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 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.

**Container Disposal:** **If empty** – Nonrefillable container. Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled** – Never place unused product down any indoor or outdoor drain. Batch Code \_\_\_\_\_

**CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY**

This product is reasonably fit for the purposes described on the label when used in strict accordance with label instructions. The manufacturer is not responsible for any use of this product that is contrary to the label instructions on the container, or under abnormal conditions that are not reasonably foreseeable by the manufacturer and or seller. The buyer assumes all risk associated with use beyond label instructions or under abnormal conditions.

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registered under EPA Reg. No. 70299-9

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## Sublabel B: Residential Directions for Use

SaniDate® Ready to Use is an activated form of hydrogen peroxide and can be used to clean, sanitize, and deodorize floors, walls, and other hard, non-porous surfaces such as linoleum, vinyl, porcelain tile, plastic polyethylene, stainless steel, and glass.

SaniDate® Ready to Use is an effective sanitizer against gram positive and gram negative bacteria such as *Staphylococcus aureus* (Staph) and *Klebsiella pneumoniae*.

SaniDate® Ready to Use is for the sanitization of hard, non-porous food contact surfaces. Use SaniDate® Ready to Use to kill *Staphylococcus aureus* (Staph), *Salmonella enterica* (Salmonella) and *Escherichia coli* (E. coli) in kitchens and food preparation areas on countertops, tabletops, stovetops, microwave ovens, cutting boards, sinks and appliances.

SaniDate® Ready to Use contains an activated form of hydrogen peroxide that may be used to clean fruits and vegetables.

SaniDate® Ready to Use will help remove pesticide residues, chemicals, and soil, as well as spoilage and decay organisms on the surfaces of fruit and vegetables.

Use SaniDate® Ready to Use as a fungicide/bactericide to treat/control plant diseases on all flowering plants, ornamentals, house plants, vegetable, berry and fruit plants and trees.

SaniDate® Ready to Use is a preventative treatment for suppressing plant diseases such as – *Alternaria* – *Anthraco*se – *Aphanomyces* – Black Spot - *Botrytis* (grey mold) - Downy Mildew – *Erwinia*, *Fusarium* (root rot) - Leaf Spot - *Phytophthora* (blights, rots) – *Plasmopara* - Powdery Mildew - *Pseudomonas* - *Pythium* - *Rhizoctonia* - Rust - Scab - Smut - *Thielaviopsis* – *Uncinula* (powdery mildew) – *Xanthomonas* - Wilts & Blights - *Ralstonia solanacearum* (brown rot, bacterial wilt), - *Sclerotinia sclerotiorum* (white mold).

### DIRECTIONS FOR USE

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

### APPLICATION INSTRUCTIONS:

(For Spray Bottle) Turn nozzle to “spray” or “stream”. Spray 6 to 8 inches from surface.

#### **Sanitization of Hard, Non-Porous Surfaces**

To Sanitize: Remove gross filth. Pre-clean hard, non-porous surfaces to be treated with a recommended detergent, or with a cleaning treatment of SaniDate® Ready to Use. Spray until thoroughly wet; *do not dilute*. Let stand 5 minutes and then air dry. No potable rinse is required.

#### **Sanitization of Hard, Non-Porous Food Contact Surfaces**

To Sanitize: Remove gross food particles. Pre-clean hard, non-porous surfaces to be treated with a recommended detergent, followed by a potable water rinse. Spray until thoroughly wet; *do not dilute*. Let stand 1 minute. If desired, wipe with paper towel or clean dish towel. Allow to air dry. Do not rinse.

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amended, for the purpose of  
registered under EPA Reg. No.

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**Fruit and Vegetable Treatment**

Fruit and Vegetable Wash: Rinse with clean water to remove excess soil. Spray all fruit or vegetable surfaces until wet with SaniDate® Ready to Use. Rub produce for 30-60 seconds. Thoroughly rinse produce under clean running water to remove soil and excess cleaner.

**Plant Disease Treatment**

Vegetables, Fruit Trees, Flowers, Ornamentals, Houseplants, Trees and Shrubs: Apply at the first sign of disease. Apply SaniDate® Ready to Use to all plant surfaces. Spray foliage to point of runoff. Apply consecutive treatments until control is achieved.

Note: SaniDate® Ready to Use has not been tested all plant species, it is always advisable to test SaniDate® Ready to Use on a small number of plants before treating large numbers. Do not apply to wilted plants.

**APPLICATION INSTRUCTIONS:**

**(For 1 or 5 Gallon Container)** Pour required amount into bucket; *do not dilute*. Apply solution with a mop, cloth, sponge, brush, scrubber, or coarse spray device, or by soaking to completely immerse all surfaces to be treated.

**Sanitization of Hard, Non-Porous Surfaces**

To Sanitize: Remove gross filth. Pre-clean hard, non-porous surfaces to be treated with a recommended detergent or with a cleaning treatment of SaniDate® Ready to Use, and rinse well with potable water. Apply fresh solution to surface until thoroughly wet; *do not dilute*. Let stand for 5 minutes and then air dry. No potable rinse is required.

**Sanitization of Hard, Non-Porous Food Contact Surfaces**

To Sanitize: Remove gross food particles. Pre-clean hard, non-porous surfaces to be treated with a recommended detergent, followed by a potable water rinse. Apply SaniDate® Ready to Use to surface until thoroughly wet; *do not dilute*. Let stand 1 minute. If desired, wipe with paper towel or clean dish towel. Allow to air dry. Do not rinse.

**Fruit and Vegetable Treatment**

Fruit and Vegetable Wash: Pour solution into a container and let fruit and vegetables soak in the solution for a minimum of 30-60 seconds. Rub or swish as needed. Thoroughly rinse produce under clean running water to remove soil and excess cleaner.

**Plant Disease Treatment**

Vegetables, Fruit Trees, Flowers, Ornamentals, Houseplants, Trees and Shrubs: Apply at the first sign of disease. Using a hand held sprayer, apply SaniDate® Ready to Use to all plant surfaces. Do not dilute. Spray foliage to point of runoff. Apply consecutive treatments until control is achieved.

Interiorscapes, House Plants, Potted Plants, Seedlings, Ornamentals: Use SaniDate® Ready to Use as a soil or media drench to control / suppress soil borne plant diseases. Use as a soil drench at the time of seeding or transplanting, and on potting soil and growing mediums prior to planting. Apply to soil or growing media to the point of saturation. Wait fifteen minutes before planting or watering.

Note: SaniDate® Ready to Use has not been tested all plant species, it is always advisable to test SaniDate® Ready to Use on a small number of plants before treating large numbers. Do not apply to wilted plants.

**ACCEPTED**  
with **COMMENTS**

• **EPA Letter Dated:**

**NOV 18 2010**

**SaniDate® Ready to Use; EPA Reg. No. 70299-9**

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**STORAGE AND DISPOSAL**

Store this product in a cool place. Keep out of direct sunlight. Do not freeze. Nonrefillable container. Do not reuse or refill this container. -or- Refill only with this product. Do not reuse or refill except as described in the directions for use. Place in trash or offer for recycling if available. Call your local solid waste agency for disposal instructions.

**CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY**

This product is reasonably fit for the purposes described on the label when used in strict accordance with label instructions. The manufacturer is not responsible for any use of this product that is contrary to the label instructions on the container, or under abnormal conditions that are not reasonably foreseeable by the manufacturer and or seller. The buyer assumes all risk associated with use beyond label instructions or under abnormal conditions.

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**Optional Label Claims:**

- Easy to use
- For sanitizing of hard, non-porous surfaces, structures & equipment
- Activated Peroxide Sanitizer for Hard Non-Porous Surfaces and Food Preparation Areas
- Hard Surface Sanitizer
- Ready to use Activated Peroxide Sanitizer
- Contains no phosphates
- Sanitizes and deodorizes
- Leaves no residue
- Scent free
- Chlorine free
- Kills 99.9% of Bacteria! \* \**Staphylococcus aureus (Staph)*, *Klebsiella pneumoniae*, *Escherichia coli (E. coli)*, and *Salmonella enterica (Salmonella)*
- Versatile Sanitizer
- Ready to Use treatment for healthier plants
- Ready to Use treatment for the prevention and control of plant diseases
- For use in home gardens
- Fruit and Vegetable Wash
- Makes fruits and vegetables cleaner
- Keeps fruits and vegetables fresher
- Leaves fruits and vegetables clean with no residue
- Reduces spoilage
- Controls the growth of spoilage and decay causing organisms
- Fruits and vegetables last longer
- Helps oxygenate the soil
- Use SaniDate® Ready to Use to sanitize hard, non-porous food contact surfaces
- Sanitizes kitchen countertops, tabletops, stovetops, microwave ovens, sinks, and appliances
- Leaves household surfaces sanitized
- Sanitizes food preparation areas
- Kills odor causing bacteria
- Use throughout the home
- Use for a cleaner kitchen
- Ready to Use
- Use for a fresher kitchen
- Peroxide Sanitizer
- Leaves no harmful residue
- Deodorizes
- Deodorizes kitchen surfaces
- Removes stains
- Removes pet stains
- Color safe
- Contains no harsh chemicals
- Contains no abrasives
- For daily use
- Sanitizes food preparation areas without rinsing
- Antibacterial

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- Kills 99.9% of bacteria that can cause foodborne illnesses
- Kills 99.9% of bacteria that can cause food poisoning
- Kills odor causing bacteria
- Breaks down into oxygen and water
- Removes surface contamination from produce
- Leaves no aftertaste or smell
- Reduced spoilage
- Easy
- Convenient
- No rinsing
- Sanitizes while you clean

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

NOV 18 2010

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
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registered under EPA Reg. No. 70299-7