

70299-9

05-25-2007

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U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number:

70299-9

Date of Issuance:

MAY 25 2007

Term of Issuance:

Conditional

Name of Pesticide Product:

SaniDate® Ready to Use

NOTICE OF PESTICIDE:

[x] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Donna Bishel
BioSafe Systems
22 Meadow St.
East Hartford, CT 06108

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(a) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
a. Revise the "EPA Registration Number to read, "EPA Reg. No. "70299-9".

Signature of Approving Official:

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

Date:

MAY 25 2007

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- b. On page 2, under the **SURFACE SANITATION** section, delete the organism *Escherichia coli*. Data were only provided to support efficacy against *Staphylococcus aureus* and *Klebsiella pneumoniae*.
- c. On page 2, under the **APPLICATION INSTRUCTIONS** section, delete the following statement, "General Cleaning: Spray product directly on to soils and wipe clean with a dry paper towel or lint free cloth". Repeat for heavily soiled surfaces" This claim is unacceptable and misleading because submitted data were not conducted in the presence of organic soil.
- d. On page 2, under the **APPLICATION INSTRUCTIONS** section, after the wording, "To Sanitize", add the language "Remove Gross Filth".
- e. On page 2, , under the **APPLICATION INSTRUCTIONS**, in the section stated "To Sanitize", delete "30 seconds", and in its place, insert "5 minutes". Submitted data stated that testing was conducted at a 5 minute contact time.
- f. On page 3, in the **General Cleaning** section, remove the entire statement. This claim is unacceptable and misleading because submitted data were not conducted in the presence of organic soil.
- g. On page 3, after the wording, "To Sanitize", add the language "Remove Gross Filth".
- h. On page 3, in the section that states "To Sanitize", delete "30 seconds", and in its place, insert "5 minutes". Submitted data stated that testing was conducted at a 5 minute contact time.
- i. On page 3, the sections **SANITIZING AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARNs, KENNELS, HUTCHES)** and **SANITATION OF NON-FOOD CONTACT PACKAGING EQUIPMENT** must be removed. These claims are not consistent with submitted efficacy data and, therefore, must be deleted.
- j. On page 5, in the section that states "SaniDate® Ready to Use is an effective sanitizer..." delete the organism, *Escherichia coli*.
- k. On page 5, Under **DIRECTIONS FOR USE**, in the section that states "**Application Instructions**", delete the following statements (listed twice): "General Cleaning: Spray product directly on to soils and wipe clean with a dry paper towel or lint free cloth". In that same section, after "To Sanitize", twice add the language, "Remove Gross Filth". In addition, wherever it states "30 seconds", delete that statement and add the following language, "5 minutes".
- l. On page 7, after the statement "Kills 99.9% of Bacteria", delete *Escherichia coli* (*E. Coli*).

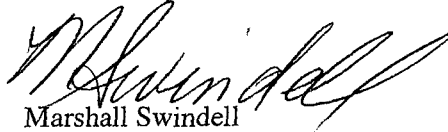
If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Demson Fuller at (703) 308-8062.

Sincerely,



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

Enclosure: (Stamped Label)

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SANIDATE®

Ready to Use

Sublabel A: Commercial Directions for Use
Sublabel B: Residential Directions for Use

Active Ingredient:
Hydrogen Peroxide 0.108%
Other Ingredients:..... 99.892%
Total:..... 100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION

FIRST AID	
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately 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.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-222-1222 for emergency medical treatment information.	

See (back) (side) (inside) panel for additional precautionary statements and directions for use.

EPA Registration No. (pending as 70299-O)
EPA Establishment No. 68660-TX-001; 58996-MO-001

Sold by:
BioSafe Systems
22 Meadow Street
East Hartford, CT 06108

Net Contents: (32 fl oz, 2 liter, 1 and 5 gallon(s))

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAY 25 2007

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No
70299-9

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Sublabel A: Commercial Directions for Use

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters or rinsate. [For 5 gallon products only] 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 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 of Regional Office of the EPA.

SURFACE SANITATION

SANIDATE® Ready to Use is an effective sanitizer against gram positive and gram negative bacteria (vegetative forms) such as *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, refrigerators, coolers, tile, and use sites listed on this label made of linoleum, vinyl, porcelain, plastic (such as polyethylene), 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.

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.

~~General Cleaning: Spray product directly on to soils and wipe clean with a dry paper towel or lint free cloth. Repeat for heavily soiled surfaces.~~

To Sanitize: Pre-clean 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~~ ~~5~~ minutes, and then air dry. No potable rinse is required.

17000 18
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5 minutes

ACCEPTED
with COMMENTS
in EPA Letter Dated
MAY 2 2007

SaniDate® Ready to Use; EPA Reg. No. (pending as 70299-0)
MASTER LABEL - Version (9) dated February 26, 2007

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

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(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.

General Cleaning: Apply solution directly on to soils and wipe clean. Repeat for heavily soiled surfaces.

Remove gross filth

To Sanitize: Pre-clean 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 20 minutes; and then air dry. No potable rinse is required. *5 minutes*

SANITIZING AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARN, KENNELS, HUTCHES)

When used as directed, SaniDate® Ready to Use is designed to sanitize, deodorize, and clean inanimate, hard surfaces such as walls, floors, sink tops, furniture, operation tables, kennel runs, cages, and feeding and watering equipment. In addition, SaniDate® Ready to Use will sanitize bins and cans, and any other areas that are prone to odors caused by microorganisms. Before using:

1. Remove all animals and feed from premises, vehicles and enclosures.
2. Remove all litter, manure, and gross filth from floors, walls and surfaces of barns, pens, stalls, chutes, and other facilities occupied or traversed by animals.
3. Empty all troughs, racks and other feeding and watering appliances.
4. Follow Application Directions listed for spray bottle or container.

SANITATION OF NON-FOOD CONTACT PACKAGING EQUIPMENT

Prior to using this product:

1. Remove gross soil particles from surfaces.
2. Wash with a recommended detergent solution and rinse thoroughly with potable water.
3. Apply solution according to Application Directions, and allow surfaces to drain thoroughly before operations are resumed.

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.

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

ACCEPTED
with COMMENTS
in EPA Letter Dated:

MAY 25 2007

Under the Federal Insecticide,
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SaniDate® Ready to Use; EPA Reg. No. (pending as 70299-O)
MASTER LABEL - Version (9) dated February 26, 2007
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WARRANTY

This material conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing, unfavorable temperatures, water conditions, presence of other materials, method of application, weather, watering practices, nature of soil, disease problem, condition of crop, incompatibility with other chemicals, pre-existing conditions and other conditions influencing the use of this product are beyond the control of the seller. Buyer assumes all risks associated with the use, storage, or handling of this material not in strict accordance with directions given herewith. NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.

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Sublabel B: Residential Directions for Use

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters or rinsate.

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), ~~*Escherichia coli* (E. coli)~~, and *Klebsiella pneumoniae*.

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.

~~General Cleaning: Spray product directly on to soils and wipe clean with a dry paper towel or lint free cloth. Repeat for heavily soiled surfaces.~~

Remove
gross
filth

To Sanitize: Pre-clean 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 30~~ seconds, and then air dry. No potable rinse is required. 5 minutes

(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.

~~General Cleaning: Apply solution directly on to soils and wipe clean. Repeat for heavily soiled surfaces.~~

Remove
gross
filth

To Sanitize: Pre-clean 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 30~~ seconds; and then air dry. No potable rinse is required. 5 minutes

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STORAGE AND DISPOSAL

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

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.

DISPOSAL: If empty – Do not reuse this container. Place in trash or offer for recycling if available. **If partly filled** – Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain.

WARRANTY

This material conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing, unfavorable temperatures, water conditions, presence of other materials, method of application, weather, watering practices, nature of soil, disease problem, condition of crop, incompatibility with other chemicals, pre-existing conditions and other conditions influencing the use of this product are beyond the control of the seller. Buyer assumes all risks associated with the use, storage, or handling of this material not in strict accordance with directions given herewith. **NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY IS MADE.**

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70299-9

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Optional Label Claims:

- Easy to use
- For sanitizing of hard, non-porous surfaces, structures & equipment
- Ready to use Activated Peroxide Disinfectant
- Contains no phosphates
- Sanitizes and deodorizes
- Leaves no residue
- Scent free
- Chlorine free
- Kills 99.9% of Bacteria! * *Staphylococcus aureus*, ~~_____~~, *Klebsiella pneumoniae*
- Versatile Sanitizer

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